FRED UPTON, MICHIGAN
CHAIRMAN

AL-14-001-2345

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515–6115

Majority (202) 225-2927 Minority (202) 225-3641

July 15, 2014

The Honorable Jim Jones
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Assistant Administrator Jones:

Thank you for appearing before the Subcommittee on Environment and the Economy on Tuesday, April 29, 2014, to testify at the hearing on the discussion draft entitled the "Chemicals in Commerce Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Tuesday, July 29, 2014. Your responses should be mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed to Nick. Abraham@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Silectory,

John Shimku

Chairman

Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member, Subcommittee on Environment and the Economy

Attachment

The Honorable Henry A. Waxman

Despite testimony over the past seven hearings on TSCA that the new chemicals program under current law has largely been a success, the revised draft implements a number of substantial changes to this program. These include new exemptions for articles and byproducts, as well as a new analytical standard under which EPA must determine whether or not regulation "is warranted." The purpose and effects of these changes are not clear.

1. Do other laws implemented by EPA require determinations of whether regulation "is warranted?" If so, has that standard been interpreted in the past as requiring a cost-benefit analysis? Has the "is warranted" standard posed any difficulties for implementation?

In your written testimony, you suggested that these new changes would have an adverse effect on the new chemicals program, weakening current law.

For instance, you state that EPA's risk management authorities for new chemicals under the discussion draft would be weaker than those in current TSCA.

2. Please explain this concern in detail.

The draft also weakens current law with respect to EPA's ability to respond where there is insufficient information. Under current law, when EPA receives a PMN for a new chemical and finds that there is insufficient information to evaluate the chemical's risks, EPA has a number of options, including requiring the development and submission of test data pursuant to section 4. The draft would curtail some of these authorities.

- 3. What steps would EPA have to take under the revised draft to obtain the information needed for new chemical reviews?
- 4. Would these steps take additional time and/or resources, compared to the current process, and if so, what effects could that have?

There has been consensus among a broad group of stakeholders that chemicals should be held to a risk-based safety standard under a reformed TSCA. This has been part of EPA's principles for TSCA reform since 2009. You testified that the standard in the discussion draft is a "risk/cost balancing" standard similar to what exists under current law and that it "does not align with the approach delineated in [EPA's] principles."

At the same time, you testified that EPA needs to have the flexibility to consider costs in risk management.

- 5. In EPA's view, should costs of risk management options play a role in determining whether or not a chemical meets a risk-based standard?
- 6. In EPA's view, should the Agency have discretion to consider costs in choosing among available risk-management options that would be adequate to bring a chemical into compliance with a risk-based standard?

The Honorable John D. Dingell

1. In 1976 I submitted report language in regard to weaknesses that exist in the current Toxic Substances Controlled Act. I stated it was essential for the protection of public health and the environment that EPA

have a firm mandate for a comprehensive approach to protection from hazards due to chemical substances. And, that such a success could only be achieved through legislative directives and adequate funding support. Mr. Jones, you state in your testimony that, in order to be successful, EPA must have the resources it needs to protect the American people from exposure to harmful chemicals.

- a. Under CICA, does EPA have the appropriate resources to quickly and efficiently implement the various framework, process, criteria, and guidance provisions which must be in place prior to EPA beginning action on specific chemicals?
- b. Under CICA, once EPA is able to take action on a specific chemical, does EPA have the resources needed to quickly and efficiently determine prioritizations, assessments, determinations, and risk managements?
- EPA has over 84,000 chemicals listed on its TSCA inventory, and little over 200 have been acted on in 37 years. EPA has identified an initial work plan of chemicals for assessment which includes 83 substances, in addition to identifying several hundred chemicals on the Safer Chemicals Ingredients List.
 - a. Under current TSCA, does EPA have the appropriate resources to complete more than 20 risk assessments per year on existing chemicals? Please answer yes or no.
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- 3. As you know, I have the privilege to live in the Great Lakes region, home to 20 percent of the world's fresh water supply as well as tremendous hunting and fishing areas. Many of my constituents have voiced concerns that CICA does not ensure adequate public health and safety standards needed for high-risk toxic chemical contamination found in this region.
 - a. Would EPA be better able to regulate new and existing chemicals if they were granted the authority to set priorities for conducting safety reviews based on relevant risk and exposure conditions?
 - b. If both chemical manufacturers and EPA had the ability to asses and act on priority chemicals like those potentially found in the Great Lakes, would EPA be better able to regulate those chemicals in a timely manner?



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 2 5 2014

OFFICE OF CONGRESSIONAL AND INTERGOVERNMENTAL RELATIONS

The Honorable John Shimkus Chairman Subcommittee on Environment and the Economy Committee on Energy and Commerce U.S. House of Representatives Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for the opportunity to respond to the questions for the record following the April 29, 2014, hearing on the discussion draft entitled the "Chemicals in Commerce Act." Enclosed are the EPA's responses to the questions.

If you have any further questions, please contact me or your staff may contact Sven-Erik Kaiser in my office at kaiser.sven-erik@epa.gov or (202) 566-2753.

Sincerely,

Nichole Distefano

Deputy Associate Administrator Office of Congressional Affairs

Enclosure

House Committee on Energy and Commerce Subcommittee on Environment and Economy Hearing on "Chemicals in Commerce Act" April 29, 2014 Questions for the Record

The Honorable Henry A. Waxman

Waxman 1. Despite testimony over the past seven hearings on TSCA that the new chemicals program under current law has largely been a success, the revised draft implements a number of substantial changes to this program. These include new exemptions for articles and byproducts, as well as a new analytical standard under which EPA must determine whether or not regulation "is warranted." The purpose and effects of these changes are not clear.

Do other laws implemented by EPA require determinations of whether regulation "is warranted?" If so, has that standard been interpreted in the past as requiring a cost-benefit analysis? Has the "is warranted" standard posed any difficulties for implementation?

Response: As noted below, the EPA identified the phrase "is warranted" (or a close variant) in several statutes it administers. Setting aside a statutory provision concerning motor vehicle warranties under Clean Air Act section 207 (using "warrant" in a different sense), the identified references are as follows:

- The Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(g)(2)(C) discusses revisions to certain previously issued regulations or orders that are "found to be warranted" after reviewing the arguments of the parties in a proceeding under FFDCA section 408(g)(2). There is also language in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 4(g)(2)(E)(v) relating to such follow-up proceedings under FIFRA or the FFDCA as "are warranted," in light of a reregistration decision. In both cases, the EPA interprets "warranted" as a direction to act in a manner that is appropriate and consistent with the underlying statutory standards that are being administered under FIFRA or the FFDCA. The EPA has not interpreted this phrase as altering or impeding the implementation of the underlying statutory standards of FIFRA or the FFDCA.
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database "if such evaluation is warranted" for possible listing on the National Priorities List (NPL). The EPA has not stated how it interprets the phrase "if such evaluation is warranted." The EPA has not interpreted it to provide for any cost-benefit analysis. CERCLA section 104(k)(3)(A)(ii) provides for the EPA to establish a program to provide cleanup grants to "eligible entities or nonprofit organizations, where warranted, as determined by [EPA] based on considerations [set forth in] subparagraph (C)." (emphasis added). Section 104(k)(3)(B) provides that eligible entities who receive a grant may in turn give cleanup sub-grants to other eligible entities or nonprofit organizations, "where warranted." Subparagraph (C) further provides a number of considerations for the EPA to consider in determining whether a grant "is warranted." The EPA does consider certain benefits as required by the considerations listed in section 104(k)(3)(C) (e.g., extent to which a grant will facility the creation or preservation of parks)." Pursuant to these provisions, the EPA has developed proposal guidelines for grants which contains ranking criteria. Applicants respond to the ranking criteria in their proposals, and proposals that pass threshold criteria review are then evaluated and scored by national panels. Proposals are selected for awards based on these scores, the availability of funds, and other factors. The EPA has not interpreted this provision to require any cost-benefit analysis.

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requirement for the EPA to complete certain studies to support development of rules that
have since been completed. Those studies were to include toxicological investigation, as
well as "if warranted" epidemiological studies, related to disinfectants and disinfectant
byproducts.

Waxman 2. In your written testimony, you suggested that these new changes would have an adverse effect on the new chemicals program, weakening current law.

For instance, you state that EPA's risk management authorities for new chemicals under the discussion draft would be weaker than those in current TSCA.

Please explain this concern in detail.

Response: Under the current Toxic Substances Control Act (TSCA) section 5(e), when the EPA has insufficient information on a new chemical substance, the EPA may issue a proposed order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance, either where such substance "may present an unreasonable risk," [TSCA section 5(e)(1)(A)(ii)(1)], or where the substance will be produced in substantial quantities and there is sufficient potential for environmental release or human exposure [TSCA section 5(e)(1)(A)(ii)(1)].

The draft of the Chemicals in Commerce Act (CICA) section 5(c)(5) appears to limit risk management actions for new chemicals to those circumstances where the EPA could establish (within the applicable review period allowed for reviewing a pre-manufacturing notice) that a particular action is "necessary to protect adequately against an unreasonable risk." This is a more demanding standard than either of the current risk management standards for new chemicals in TSCA section 5(e).

Waxman 3. The draft also weakens current law with respect to EPA's ability to respond where there is insufficient information. Under current law, when EPA receives a PMN for a new chemical and finds that there is insufficient inform1ation to evaluate the chemical's risks, EPA has a number of options, including requiring the development and submission of test data pursuant to section 4. The draft would curtail some of these authorities.

What steps would EPA have to take under the revised draft to obtain the information needed for new chemical reviews?

Response: With respect to circumstances where the Administrator finds that additional information is necessary in order to review a pre-manufacture notice, CICA section 5(c)(2)(B)(i) appears to specify that the EPA must first provide an opportunity for the submitter of the notice to voluntarily submit the additional information and/or voluntarily extend the review period. Where this is unsuccessful, under CICA section 5(c)(5) it appears that the EPA would next need to determine (within the remainder of the applicable review period) that the development of additional information was "necessary to protect adequately against an unreasonable risk."

Waxman 4. Would these steps take additional time and/or resources, compared to the current process, and if so, what effects could that have?

Response: The EPA has not undertaken an exercise to estimate the time or resources that would be needed to implement CICA, compared to the current process.

Waxman 5. There has been consensus among a broad group of stakeholders that chemicals should be held to a risk-based safety standard under a reformed TSCA. This has been part of EPA's principles for TSCA reform since 2009. You testified that the standard in the discussion draft is a "risk/cost balancing" standard similar to what exists under current law and that it "does not align with the approach delineated in [EPA's] principles."

At the same time, you testified that EPA needs to have the flexibility to consider costs in risk management.

In EPA's view, should costs of risk management options play a role in determining whether or not a chemical meets a risk-based standard?

Response: As stated in Principle 1 of the "Essential Principles for Reform of Chemicals Management Legislation" (http://www.epa.gov/oppt/existingchemicals/pubs/principles.html), the EPA should have clear authority to assess chemicals against a risk-based safety standard based on sound science and risk-based criteria protective of human health and the environment, which would not include a consideration of costs.

Waxman 6. In EPA's view, should the Agency have discretion to consider costs in choosing among available risk management options that would be adequate to bring a chemical into compliance with a risk-based standard?

Response: As stated in Principle 3 of the "Essential Principles for Reform of Chemicals Management Legislation", when addressing chemicals that do not meet the safety standard, the EPA should have the flexibility to make risk management decisions that take into account a range of considerations, including children's health, economic costs and availability of substitutes, social benefits, and equity concerns.

The Honorable John D. Dingell

Dingell 1. In 1976, I submitted report language in regard to weaknesses that existing in the current Toxic Substances Control Act. I stated it was essential for the protection of public health and environment that EPA have a firm mandate for a comprehensive approach to protection from hazards due to chemical substances. And, that such a success could only be achieved through legislative directions and adequate support funding. Mr. Jones, you state in your testimony that, in order to be successful, EPA must have the resources it needs to protect the American people from exposure to harmful chemicals.

Dingell 1a. Under CICA, does EPA have the appropriate resources to quickly and efficiently implement the various framework, process, criteria, and guidance provisions which must be in place prior to EPA beginning action on specific chemicals?

Response: CICA does not include provisions to collect fees. As outlined in the Administration's TSCA Reform Principles, implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that the EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of agency implementation, including the review of information provided by manufacturers.

Dingell 1b. Under CICA, once EPA is able to take action on a specific chemical, does EPA have the resources needed to quickly and efficiently determine prioritizations, assessments, determinations, and risk managements?

Response: The EPA has not yet assessed the resources that would be required to take action under CICA.

Dingell 2. EPA has over 84,000 chemicals listed on its TSCA inventory, and little over 200 have been acted on in 37 years. EPA has identified an initial work plan of chemicals for assessment which includes 83 substances, in addition to identifying several hundred chemicals on the Safer Chemicals Ingredients List.

Dingell 2a. Under current TSCA, does EPA have the appropriate resources to complete more than 20 risk assessments per year on existing chemicals? Please answer yes or no.

Response: No.

Dingell 2b. What kind of resources would EPA need in order to perform 10 to 20 more additional risk assessments per year?

Response: With current resources, the EPA is able to produce about ten assessments a year.

Dingell 3. As you know, I have the privilege to live in the Great Lakes region, home to 20 percent of the world's fresh water supply as well as tremendous hunting and fishing areas. Many of my constituents have voiced concerns that CICA does not ensure adequate public health and safety standards needed for highly toxic chemical contamination found in this region.

Dingell 3a. Would EPA be better able to regulate new and existing chemicals if they were granted the authority to set priorities for conducting safety reviews based on relevant risk and exposure conditions?

Response: As outlined in Principle 4 of the "Essential Principles for Reform of Chemicals Management Legislation," the EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations.

Dingell 3b. If both chemical manufacturers and EPA had the ability to asses and act on priority chemicals like those potentially found in the Great Lakes, would EPA be better able to regulate those chemicals in a timely manner?

Response: As outlined in the Administration Principles, the EPA should have the ability to assess and act on priority chemicals in a timely manner.

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FRED UPTON, MICHIGAN
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HENRY A. WAXMAN, CALIFORNIA RANKING MEMBER

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COMMITTEE ON ENERGY AND COMMERCE

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July 15, 2014

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Dingell 1b. Under CICA, once EPA is able to take action on a specific chemical, does EPA have the resources needed to quickly and efficiently determine prioritizations, assessments, determinations, and risk managements?

Response: The EPA has not yet assessed the resources that would be required to take action under CICA.

Dingell 2. EPA has over 84,000 chemicals listed on its TSCA inventory, and little over 200 have been acted on in 37 years. EPA has identified an initial work plan of chemicals for assessment which includes 83 substances, in addition to identifying several hundred chemicals on the Safer Chemicals Ingredients List.

Dingell 2a. Under current TSCA, does EPA have the appropriate resources to complete more than 20 risk assessments per year on existing chemicals? Please answer yes or no.

Response: No.

Dingell 2b. What kind of resources would EPA need in order to perform 10 to 20 more additional risk assessments per year?

Response: With current resources, the EPA is able to produce about ten assessments a year.

Dingell 3. As you know, I have the privilege to live in the Great Lakes region, home to 20 percent of the world's fresh water supply as well as tremendous hunting and fishing areas. Many of my constituents have voiced concerns that CICA does not ensure adequate public health and safety standards needed for highly toxic chemical contamination found in this region.

Dingell 3a. Would EPA be better able to regulate new and existing chemicals if they were granted the authority to set priorities for conducting safety reviews based on relevant risk and exposure conditions?

Response: As outlined in Principle 4 of the "Essential Principles for Reform of Chemicals Management Legislation," the EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations.

Dingell 3b. If both chemical manufacturers and EPA had the ability to asses and act on priority chemicals like those potentially found in the Great Lakes, would EPA be better able to regulate those chemicals in a timely manner?

Response: As outlined in the Administration Principles, the EPA should have the ability to assess and act on priority chemicals in a timely manner.

AL-14-001-3929 912-352-0105 T-977 P0002/0003 F-522

JACK KINGSTON 1st District, Georgia

WASHINGTON OFFICE 2372 Reyburn House Office Building Washington, DC 20516 (202) 225-5831 (202) 226-2269 FAX

BRUNSWICK OFFICE 1510 Newcastle Street Suite 200 Brunswick, GA 31520 (912) 265–9010 (912) 265–9013 FAX



Committee On Appropriations Chairman, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

and Related Agencies

Defense Subcommittee

State, Foreign Operations,
and Related Agencies Subcommittee

SAVANNAH OFFICE One Diamond Causeway, Suite 7 Savannah, GA 31406 (912) 352-0101 (912) 352-0106 FAX

Congress of the United States

House of Representatives

August 13, 2014

Ms. Laura Vaught
Associate Administrator for Congressional Affairs
Environmental Protection Agency
1200 Pennsylvania Ave, NW, Room 3426 ARN
Washington, D.C. 20460

Dear Ms. Vaught:

One of my constituents, which I believe your agency could be helpful. Therefore, the enclosed communication is submitted for your review.

I would very much appreciate your responding to the points raised by my constituent, and providing any assistance available under the applicable laws and regulations.

The contact person on my staff for this case is Mr. Bruce Bazemore. He can be reached at (912) 352-0101 or Bruce.Bazemore@mail.house.gov.

Thank you very much for your consideration and for advising me of any action you take in this matter.

Sincerely,

Jack Kingston

Member of Congress

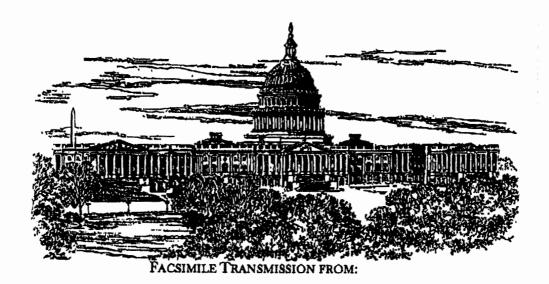
Reply to: Bruce Bazemore Congressman Jack Kingston 1 Diamond Causeway, Suite 7 Savannah, GA 31406



Congress of the United States bouse of Representatives Washington, DC 20515

CONSTITUENT CONTACT FORM Please Print Clearly-Check All Spellings

Staff: BB	CONSTITUENT ID:	a-t-parie
DATE: 7 / 14/14	LA Assigned:	
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CONGRESSMAN JACK KINGSTON

1 DIAMOND CAUSEWAY, SUITE 7 SAVANNAH, GA 31406

VOICE# (912) 352-0101 FAX# (912) 352-0105

To:	EPA Legis.	DATE:
FAX#:_	202-501-15/9	TOTAL PAGES: 3
FROM:	TRISH DEPRIEST	BRUCE BAZEMORE
	BRIANNA FORAN	☐ BROOKE CHILDERS
	OTHER	
Commo	ents:	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C., 20460

NOV - 6 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Honorable Jack Kingston U.S. House of Representatives Washington, D.C. 20515

Dear Congressman Kingston:

Thank you for your August 13, 2014, letter requesting information on behalf of your constituent, LYLINGTO , on recent U.S. Environmental Protection Agency rulemakings on flame retardants, and expressing your concern about protecting our environment and water resources from chemical pollution. These are top concerns for the EPA, with ensuring the safety of chemicals being the focus of my office, the Office of Chemical Safety and Pollution Prevention.

Today we have a better understanding of the environmental impacts, exposure pathways, and effects that some chemicals can have on human health, including flame retardant chemicals. The EPA has taken a range of regulatory actions on flame retardant chemicals in both our new and existing chemicals programs under the Toxic Substances Control Act (TSCA) over the last several years. The EPA also helped to facilitate voluntary commitments to cease production of some of these chemicals. For example:

- In 2004, the only U.S. manufacturers of the flame retardants pentaBDE and octaBDE completed a voluntary phase-out of the chemicals.
- In 2009, the EPA released an Action Plan on PBDEs (including pentaBDE, octaBDE, and decaBDE) and in 2010, released an Action Plan on the flame retardant, hexabromocyclododecane (HBCD). These Action Plans summarized available hazard, exposure and use information, outlined potential risks, and identified specific steps the agency would take to address concerns with both PBDEs and HBCD.
- In 2009, the principal domestic manufacturers and importers of decaBDE committed to end
 production, importation, and sales of decaBDE for most uses in the U.S. by December 31,
 2012, and for all uses by the end of 2013.
- In 2012, the EPA proposed a Significant New Use Rule (SNUR) that would require notification to the EPA ninety days prior to manufacture (including import) or processing for any use of pentaBDE, octaBDE and decaBDE that is not ongoing, including in articles.
- In the spring of 2013, as part of the agency's TSCA Work Plan to assess the risks of a range of chemicals, the EPA outlined a strategy for assessing more than 20 flame retardant chemicals to identify potential concerns and consider action, as appropriate, if risks are identified. This effort is currently underway.
- Most recently, the EPA has worked with stakeholders through the Design for the Environment (DfE) Alternatives Assessment Program to identify safer alternatives to PBDEs used in flexible polyurethane foam, HBCD, and a number of other flame retardant chemicals.
- Newly developed chemical alternatives are reviewed under TSCA's new chemicals program. If during this review, the EPA finds that the alternative demonstrates similar human health

and/or environmental concerns to the chemical it is intended to replace, the EPA may prohibit or place restrictions on the chemical alternative.

The actions outlined above have and will continue to help reduce the use and release of potentially harmful flame retardant chemicals.

Your letter also requests information on the relationship between chemical spills along the Ogeechee River in Georgia and the James River in Virginia. Under the Clean Water Act, state agencies in these two states play the lead day-to-day role in ensuring compliance with the Clean Water Act, with the EPA serving in a capacity to provide oversight and assistance, as appropriate. The EPA shares your overall concerns regarding the potential harmful effects of chemical spills on our environment and works on a daily basis with state and federal agencies, including the Department of Justice, as appropriate, to help respond to—and prevent—such incidents.

Again, thank you for your letter and I hope the information provided is helpful to you. If you have any further questions, please contact me, or your staff may contact Mr. Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at (202) 564-2753 or Kaiser. Sven-Erik@epa.gov.

Sincerely,

James J. Jones | \| Assistant Administrator

AL-14-001-3899

THOMAS R. CARPER, DELAWARE, CHAIRMAN

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United States Senate

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS WASHINGTON, DC 20510-6250

August 6, 2014

The Honorable Gina McCarthy
Administrator of the Environmental Protection Agency
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator McCarthy:

During this period of difficult fiscal challenges, it is critical that federal agencies act prudently when making spending decisions, especially when they decide to employ outside vendors. In certain cases, hiring contractors to complete specific tasks or assignments is necessary, and it can be an economical way for government agencies to fulfill their missions. However, it is essential that agencies are fully transparent about relations with government contractors and make objectives clear when outside vendors are hired.

It has recently come to my attention that some agencies are hiring contractors to monitor news articles, editorials, and journalism projects that mention the agency and then rate each story accordingly as positive, negative, or neutral. Tracking media coverage in this manner may inhibit news outlets' communications with federal agencies and restrict the flow of public information.

It is understandable that agencies strive for awareness of how their actions and practices are being portrayed in the media. However, spending appropriated funds on outside contractors to rate media coverage without appropriate transparency efforts is an inefficient use of agency resources.

To help me gain a better understanding of how the Environmental Protection Agency handles the monitoring of news coverage, please provide answers to the following questions:

- 1) Does the Agency employ an outside vendor to monitor and track news articles, editorials, and other journalism publications that implicate the Agency?
- 2) If the answer to Question 1 is "yes," please also provide answers to the questions below:
 - a) Is the vendor instructed to rate each news publication or story as positive, negative, or neutral?
 - b) How does the Agency utilize the information compiled by the vendor?
 - c) What vendor did you hire to complete this task?
 - d) What was the cost of hiring such a vendor in Fiscal Year 2014?

- 3) Are any full-time employees at the Agency responsible for monitor and tracking news articles, editorials, and other journalism publications that implicate the Agency?
- 4) If the answer to Question 3 is "yes," please also provide answers to the questions below:
 - a) Are such employees instructed to rate each news publication or story as positive, negative, or neutral?
 - b) How many employees at the Agency are responsible for this work?
 - c) What are the titles of such employees?
 - d) What are the annual salaries of such employees?

Your response is requested no later than August 20, 2014. Thank you for your attention to this important matter. If you have any questions about this request, please contact Sally Braeuer on my staff at (202) 224-4597 or via email at SallyAnne_Braeuer@hsgac.senate.gov.

Sincerely,

Tom A. Coburn, M.D.

Ranking Member

Committee on Homeland Security and

Governmental Affairs

AL-14-001-4396

BARBARA BOXER, CALIFORNIA, CHAIRMAN

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BETTINA POIRIER, MAJORITY STAFF DIRECTOR
ZAK BAIG, REPUBLICAN STAFF DIRECTOR

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

August 26, 2014

The Honorable Jim Jones Assistant Administrator Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW Washington, DC 20460

Dear Assistant Administrator Jones:

Our work to unravel the depth and breadth of mismanagement at the U.S. Environmental Protection Agency (EPA) requires forthright and thorough responses. Your response on July 21, 2014 to our previous letter² regarding the trichloroethylene (TCE) assessment and senior manager Dr. Stan Barone failed to provide a full accounting of what was requested. Therefore, the courtesy previously extended to avoid additional information being made public on these matters must be withdrawn.

On June 25, 2014, you were asked by several members of the United States Senate to provide information pertaining to the work product and promotion of Dr. Barone. At this stage you have failed to comply. For example, you stated in your letter dated July 21, 2014 that Dr. Barone's change in position from a Branch Chief to a Deputy Division Director was "a noncompetitive lateral move, with no change in pay grade or salary." However, you were reminded in the June 25, 2014 letter that "...promoting an employee (i.e. Dr. Stan Barone) or demoting an employee requires strict compliance with established rules of prohibited personnel practices." As described under 5 U.S.C. §2302(a)(2)(A), a personnel action means: "an appointment," "a promotion," "a detail, transfer, or reassignment," "a decision concerning pay, benefits, or awards...," or "any other significant change in duties, responsibilities, or working conditions."5

We are unwilling to accept your assertion that Dr. Barone's transfer from a Branch Chief to a Deputy Division Director was not a promotion, and request your interpretation of how this

5 Id.

¹ Letter from Hon. Jim Jones, Assistant Adm'r, Office of Chemical Safety & Pollution Prevention, U.S. Envtl. Prot. Agency, to Hon. David Vitter, Ranking Member, S. Comm. on Env't & Public Works (July 21, 2014) [hereinafter July 21, 2014, Letter].

² Letter from Hon. David Vitter, Ranking Member, S. Comm. on Env't & Public Works, et al., to Hon. Jim Jones, Assistant Adm'r, Office of Chemical Safety & Pollution Prevention, U.S. Envtl. Prot. Agency (June 25, 2014) [hereinafter June 25, 2014, Letter].

July 21, 2014, Letter, supra note 1.

⁴ Title 5 - Government Organization and Employees, Chapter 23 - Merit System Principles, Section 2302., Prohibited Personnel Practices, subpart b, available at http://www.gpo.gov/fdsys/pkg/USCODE-2010title5/pdf/USCODE-2010-title5-partIII-subpartA-chap23.pdf.

change was not "an appointment" or "a detail, transfer, or reassignment." When compiling your responses, please provide the following documentation:

- 1. Copies of all awards (cash and time off) that Dr. Barone received since joining the Office of Pollution Prevention and Toxics (OPPT).
- 2. Copies of Dr. Barone's position descriptions from when he was hired as an OPPT Branch Chief and when he was hired as an OPPT Deputy Division Director.
- 3. A list of Dr. Barone's direct reports when he was an OPPT Branch Chief, and his current list of direct reports as the Deputy Division Director.

We are quite certain that as you compile your responses to the foregoing requests you will realize that: 1) Dr. Barone's "noncompetitive lateral move" was a personnel action; 2) the Deputy Division Director position was not advertised to ensure fair and open competition; 3) Dr. Barone's promotion was essentially a gift, which hints towards some degree of personal favoritism; and 4) OPPT's senior management not only disregarded merit system principles, but also engaged in prohibited personnel practices. On a related note, we request that you provide the following information pertaining to Dr. Barone's promotion, which we requested in our original letter on June 25, 2014:

[W]e are requesting all communications related to RAD's Deputy Director's position announcement, the selection process used, and a list of individuals within RAD, who were eligible to compete for this position, based on grade and time in service, as well as your knowledge of any employees that may have been demoted to facilitate Dr. Barone's promotion.⁶

We also ask for the following information:

- 1. A copy of your position description when you served as the Deputy Administrator at the Office of Air and Radiation (OAR) between April 2011 to November 2011, along with responses to the following questions:
 - a. How many days during your tenure at OAR did you serve as the Acting Assistant Administrator?
 - b. How many times during your tenure at OAR did you approve or direct another employee to approve time and attendance or travel for OAR staff?
 - c. How many times did you discuss your concerns over John Beale's time and attendance and questionable CIA work with an OAR employee, but failed to confront Mr. Beale or to report your suspicions to the Office of the Inspector General?
- 2. On what date did you become aware that there were serious time and attendance issues at the Office of Chemical Safety and Pollution Prevention (OCSPP) and what corrective actions did you take?

⁶ June 25, 2014, Letter, supra note 2.

- 3. Who are the staffers you have taken corrective actions against, when did you decide to take those actions, and how soon after being informed of the problems did you decide to act?
- 4. Have you ever taken any retributory actions against an EPA whistleblower?
- 5. Have you ever sought to demote or otherwise undermine any Agency staff that you felt might be or you knew to be a whistleblower?
- 6. Have you ever attempted to interfere with an IG investigation or otherwise obtain information you knew to be the subject of an IG investigation?
- 7. Have you ever directed any staff to discover information being provided to the IG or to otherwise obtain information you knew to be the subject of an IG investigation?
- 8. Have you or your staff ever misrepresented information or excluded a material fact(s) when taking corrective action(s) against an employee?
- 9. Please provide copies of all communications between Ken White from the Office of Labor and Employee Relations, and Dr. Stan Barone, Dr. Kathryn Gallagher, Dr. Jennifer Seed, and Dr. Todd Stedeford.

We expect a thorough and complete response to each of the foregoing questions by September 9, 2014.

David Vitter Ranking Member

Senate Committee on Environment and Public Works

Thank you,

James Inhofe

Ranking Member

Subcommittee on Oversight

u-Clarkso

Mike Crapo

Ranking Member

Subcommittee on Superfund, Toxics, & Envtl. Health

CHAIRMAN

EDDIE BERNICE JOHNSON TUXUS EANKING MEMBER

Congress of the United States

House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 HAYBURN HOUSE OFFICE BUILDING

Washington, DC 20515-6301

(202) 225-6371 www.chence.house.gov

August 7, 2014

Dr. Kenneth Olden
Director
National Center for Environmental Assessment
U.S. Environmental Protection Agency
Two Potomac Yard
2733 South Crystal Drive
Arlington, VA 22202

Dear Dr. Olden.

On behalf of the Committee on Science, Space, and Technology, we want to express our appreciation for your participation in the July 16, 2014 hearing titled, "Status of Reforms to EPA's Integrated Risk Information System."

We have attached a verbatim transcript of the hearing for your review. The Committee's rule pertaining to the printing of transcripts is as follows:

The transcripts of those hearings conducted by the Committee and Subcommittees shall be published as a substantially verbatim account of remarks actually made during the proceedings, subject only to technical, grammatical, and typographical corrections authorized by the person making the remarks involved.

Transcript edits, if any, should be submitted no later than August 21, 2014. If no edits are received by the above date, we will presume that you have no suggested edits to the transcript.

We are also enclosing questions submitted for the record by Members of the Committee. These are questions that the Members were unable to pursue during the time allotted at the hearing, but felt were important to address as part of the official record. All of the enclosed questions must be responded to no later than August 21, 2014.

All transcript edits and responses to the enclosed questions should be submitted to us and directed to the attention of Ms. Sarah Grady at <u>Sarah Grady@mail.house.gov</u>. If you have any further questions or concerns, please contact Ms. Grady at (202) 225-6371.

Dr. Olden August 7, 2014 Page 2

Thank you again for your testimony.

Sincerely,

Ren. Paul Broun, M.D.

Chairman

Subcommittee on Oversight

Rep. David Schweikert

Chairman

Subcommittee on Environment

cc:

Rep. Dan Maffei Ranking Member

Subcommittee on Oversight

Rep. Suzanne Bonamici

Ranking Member

Subcommittee on Environment

Enclosures: Transcript, Member Questions for the Record

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY SUBCOMMITTEE ON OVERSIGIT AND SUBCOMMITTEE ON ENVIRONMENT

"Status of Reforms to EPA's Integrated Risk Information System"

QUESTIONS FOR THE RECORD

Dr. Kenneth Olden Director, National Center for Environmental Assessment, U.S. Environmental Protection Agency

Questions submitted by Chairman Broun and Chairman Schweikert

- 1. In 2011, the NAS recommended that EPA provide clear guidelines for study selection. In a true systematic review, one must develop criteria in advance, and use these criteria to evaluate study quality. Is this the correct approach? Do you believe the recent draft IRIS assessments that are currently undergoing review or will soon be reviewed (ammonia, trimethylbenzenes, ethylene oxide) transparently provide these criteria? Should systematic review be a priority for all draft assessments?
- 2. What is the most significant improvement to the IRIS program, and what continues to be the most pressing challenge?
- 3. In 2013, GAO reported that EPA's most recent evaluation of demand for IRIS assessments was a decade old. EPA had no plans to perform another evaluation, but recognized that due to changing conditions over the last 10 years, the 2003 evaluation was not applicable to current conditions.
 - a. What progress has EPA made in identifying and evaluating demand for IRIS toxicity assessments, and what report or study, if any, has EPA produced on current demand?
 - b. Given EPA's challenges in completing enough IRIS toxicity assessments to meet their annual goals (e.g., EPA completed 4 IRIS toxicity assessments in fiscal year 2012, falling short of its goal of completing 40 assessments for that year), how has EPA considered its current resource constraints when identifying how it will meet demand?

- 4. According to data on EPA's website, 90% of the 560 completed IRIS assessments are more than 10 years old and 75% are more than 20 years old. However, over those intervening years, new data on many of these chemicals may have emerged, and certainly the methods for assessment have changed over these years (for example, as identified in EPA's 2005 Cancer guidelines). In 2009, EPA instituted a project to update older assessments, and the manager of that program (Dr. Chon Shoat) was quoted as saying that the program would need to do 300 updates each decade just to keep from falling further behind. Has this program continued? In addition, organizations are urging the IRIS program to undertake assessments of yet additional chemicals not already on the list. What is the size of the current IRIS workload, and how do you propose to address it?
- 5. At the Committee's request, the EPA Inspector General issued a report last year on the use of the IRIS database by EPA program offices and regions. According to the IG's report, approximately "one-third (34 percent) of the survey respondents reported that they have used an alternate source for toxicity values when an IRIS value was available. The primary reason selected for using an alternate source was that the alternate source was more up-to-date with current scientific practice or information." Does it concern you that some of your colleagues at EPA don't use IRIS values and what will it take to fix this internal disconnect?
- 6. In light of GAO's listing of IRIS on the "High Risk" list and the acknowledgement by EPA that it needs to both reform the program and produce/update more assessments, why did the President propose to reduce funding for the program in FY2015?
- 7. What is the projected cost of a typical IRIS assessment?
- 8. A common criticism of IRIS assessments is the tendency to be "public health protective," which can lead to unrealistically conservative assessments, which, in turn, can lead to overstated environmental risks and bad regulation. We have heard the oft-repeated mantra that IRIS assessments are purely scientific and not regulatory, but doesn't a bad risk assessment restrict a risk manager's options, ultimately forcing him or her to make a bad risk management decision?
- 9. In 2009, you were part of a Bipartisan Policy Center report that unanimously recommended that "studies used in the formulation of regulation should be subject to data access requirements... regardless of who funded the study." Do you still agree with this statement? And how has this recommendation been implemented in the IRIS and National Ambient Air Quality Standard-setting process in your office?

- 10. While EPA often relies on scientific data produced by or funded by other government agencies in its assessments, those raw data are not made available to external reviewers and the public for independent evaluation. Stakeholders have tried many approaches to get these data through the Freedom of Information Act, but often come up short and if data are provided, it is not provided in a timely manner to help inform comments on the assessments. Will you ensure that all the data the IRIS program uses in its assessments are made accessible to all stakeholders (assuming appropriate privacy protections, etc...)?
- 11. IRIS assessments routinely identify one or more reference values below which no bad effects in humans are expected, and these are provided to other EPA offices and other agencies as a guide for the establishment of regulations that often require control of the chemical down to the level the IRIS program has established. Several of the chemicals under the purview of the IRIS program, including methanol and formaldehyde, are produced naturally by the human body.

In the recent final assessment of methanol, your office published a reference level that, in the case of 20% of the U.S. population, is exceeded by that person's naturally-produced methanol and is also equal to the amount of methanol that is contained in just 25 ounces of orange juice.

- a. Should EPA examine these kinds of naturally-occurring chemicals differently from other chemicals, perhaps by looking more closely at the safety margins that are built into these reference values and asking whether the resulting reference values are realistic? Do you have a plan to do so?
- 12. Could you tell us what an "adverse effect" means to you? Does EPA have any guidance on the definition of an "adverse effect," and does the IRIS program follow this guidance?
- 13. To what extent does having multiple toxicity assessment sources for the same chemical present challenges for ensuring consistent risk management across the nation, and what steps has EPA taken to either minimize or explain reasons for any differences?
- 14. Many of the well-known pollutants of concern apparently up for assessment revision by IRIS have been previously assessed by other federal health agencies— OSHA, the National Institute for Environmental Health Sciences, ATSDR, as well as other entities like the National Academy of Sciences, the World Health Organization, or the chemical industry.
 - a. What is particularly essential about the IRIS Assessment updates that justify this new batch of assessments? What health benefit might be gained?
 - b. What IRIS users/customers are calling for these new assessments?
 - c. Given that "science is science," why is an IRIS assessment superior to other assessments, including those of professional societies and industry?

- 15. You have implemented a standing set of bi-monthly meetings to address chemical specific scientific issues as well as to have discussions about problem formulation. At the most recent June meeting, it appeared that many NGOs boycotted the meeting due to concerns they said were related to not knowing about the meetings and concerns regarding too much industry representation. It is our understanding that these meetings have all been announced on the IRIS webpage, registration is open to everyone, and anyone who wishes to speak can get a slot on the agenda. Is this a fair representation of your actions to ensure that all representatives of the public are welcome to provide an input to the IRIS process, or do the arguments for the boycott have merit?
- 16. Should standard protocols be developed to enable all studies to be independently judged based on their quality, strength, and relevance, regardless of the author affiliation or funding source? If so, will you make development of these standard approaches a priority?
- 17. The science of hazard assessments has become complex in recent years. Does IRIS have the requisite staff and expertise in all the needed disciplines to draft assessments efficiently and quickly? Would a more qualified staff lead to more concise and accurate assessments, partially because much of the information in these 1,000+ page assessments could be eliminated?
- 18. Following up on our discussion in the hearing when you said you would get back to the Committee with specifics, do you anticipate the first couple of IRIS assessments that will incorporate all of the NRC recommendations to be on new chemicals, and if so, which ones, or will they be updates of old assessments?
- 19. How does EPA intend to approach more challenging IRIS reforms such as evidence integration and weight of evidence? When will EPA develop guidelines or integrate a consistent approach in actual assessments?
- 20. The testimony from Mr. Walls noted that even though EPA documents are peer reviewed, the EPA staff that write the assessments are judge and jury of which comments from the public and from peer review experts are accepted and rejected. In fact, it was brought to our attention that in the recently finalized methanol document, EPA staff used the response to comments to describe a new policy position and approach to address endogenous exposures.
 - a. Do you support such actions? Should there be an independent entity, similar to the role a journal editor plays, to review how EPA staff respond to comments before the document is finalized?
- 21. The National Research Council recommends that the IRIS handbook be peer reviewed. Has this happened? Will it? If so, when, and if not, why not?

- 22. You have recently developed a subpanel of the EPA Science Advisory Board to review IRIS assessments.
 - a. Will this panel be asked to review cross-cutting issues, like assessments of chemicals below background or endogenous exposures?
 - b. Will you take public comment on the "charge questions" asked of this panel?
 - c. Consistent with the Environmental Research, Development, and Demonstration Authorization Act, which authorizes the Science Advisory Board, will you allow this panel to answer any and all questions sent by this Committee?
- 23. The National Research Council recommends that EPA should provide technical assistance to stakeholders who don't have resources to provide input. How is EPA implementing or planning to implement this proposal fairly so that one class of stakeholders isn't overly assisted?



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT - 1 2014

OFFICE OF CONGRESSIONAL AND INTERGOVERNMENTAL RELATIONS

The Honorable Lamar Smith Chairman Committee on Science, Space, and Technology United States House of Representatives Washington, DC 20515

Dear Mr. Chairman:

Thank you for your August 7, 2014, letter and the opportunity to respond to the questions for the record from the House Committee on Science, Space, and Technology's Subcommittees on Oversight and Environment hearing on July 16, 2014, entitled *Status of Reforms to EPA's Integrated Risk Information System.* Please find our responses in the attached document.

Again, thank you for your letter. If you have further questions, please contact me, or your staff may contact Christina J. Moody, in the EPA's Office of Congressional and Intergovernmental Relations, at moody.christina@epa.gov or at (202) 564-0260.

Sincerely,

Nichole Distefano

Deputy Associate Administrator

Enclosures

ec: The Honorable Paul Broun, M.D.

The Honorable David Schweikert

The Honorable Dan Maffei

The Honorable Suzanne Bonamici

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY SUBCOMMITTEE ON OVERSIGHT & SUBCOMMITTEE ON ENVIRONMENT

Hearing Entitled
Status of Reforms to EPA's Integrated Risk Information System
July 16, 2014

QUESTIONS FOR THE RECORD

Dr. Kenneth Olden
Director, National Center for Environmental Assessment
U.S. Environmental Protection Agency

Questions submitted by Chairman Broun and Chairman Schweikert

1. In 2011, the NAS recommended that EPA provide clear guidelines for study selection. In a true systematic review, one must develop criteria in advance, and use these criteria to evaluate study quality. Is this the correct approach? Do you believe the recent draft IRIS assessments that are currently undergoing review or will soon be reviewed (ammonia, trimethylbenzenes, ethylene oxide) transparently provide these criteria? Should systematic review be a priority for all draft assessments?

Answer: EPA agrees with and is implementing the 2011 National Research Council (NRC) recommendations regarding systematic review. Consistent with the advice of the NRC in their "Roadmap to Revision" in Chapter 7 of the 2011 NRC formaldehyde review report, EPA is implementing the recommendations using a phased approach. Specifically, NRC stated that "the committee recognizes that the changes suggested would involve a multiyear process and extensive effort..." In implementing the recommendations in a phased approach, EPA has stated that the most extensive changes are being made to documents that are in earlier steps of the assessment development process. For assessments that are in the later stages of development, such as ethylene oxide, EPA is implementing some of the recommendations without taking the assessments backwards to earlier steps in the process.

In May 2014, the NRC released their report reviewing the IRIS assessment development process. In this report, the NRC commends EPA's efforts to improve IRIS and found that the program has moved forward steadily in planning for and implementing changes in each element of the assessment process. The report also noted that EPA has made substantial improvements to the IRIS Program in a short time. The report noted that, "overall, the changes that EPA has proposed and implemented to various degrees constitute substantial improvement in the IRIS process" and that "if current trajectories are maintained, inconsistencies identified in the present report are addressed, and objectives still to be implemented are successfully completed, the IRIS process will become much more effective and efficient in achieving the program's basic goal of

developing assessments that provide an evidence-based foundation for ensuring that chemical hazards are assessed and managed optimally." Of note, the committees agreed that the new document structure for IRIS assessments improves the organization of and streamlines the assessments, and the evidence tables and graphic displays of study findings increases clarity and transparency. These changes have been implemented in the draft ammonia and trimethylbenzenes assessments. The report stated that this approach brings IRIS assessments more in line with the state of practice for systematic reviews.

Additionally, we are actively working to develop, where necessary, and implement methodologies for the application of systematic review to all IRIS assessments. This topic will be discussed at the upcoming October 15-16, 2014 NRC Recommendations Workshop (http://www.epa.gov/iris/irisworkshops/NRC_workshop/index.htm). The workshop will include focused discussions with scientific experts on refining systematic review methodologies, as well as the systematic integration of evidence streams.

2. What is the most significant improvement to the IRIS program, and what continues to be the most pressing challenge?

Answer: Strengthening and streamlining the IRIS Program is an ongoing priority for EPA. On July 31, 2013, EPA announced a series of enhancements to help meet the goal of producing high quality scientific IRIS assessments in a timely and transparent manner. These enhancements focused on: 1) improving the scientific integrity of assessments; 2) improving the productivity of the program; and 3) increasing transparency so controversial or complex science issues are identified and debated early in the process. These changes are consistent with recent recommendations provided by the National Research Council.

The most significant improvement to the IRIS program is increased early engagement with the public to ensure that EPA identifies and addresses any controversial scientific issues earlier in the assessment development process. This early scientific engagement is anticipated to strengthen the overall quality of IRIS assessments. The most significant challenge facing the IRIS Program is meeting the needs of the agency in a timely manner. It is anticipated that enhanced stakeholder and public engagement will play a crucial role in ensuring transparency and the use of the best available science throughout the IRIS assessment process. As a result, the IRIS Program will be able to complete assessments in a timelier manner in the future.

- 3. In 2013, GAO reported that EPA's most recent evaluation of demand for IRIS assessments was a decade old. EPA had no plans to perform another evaluation, but recognized that due to changing conditions over the last 10 years, the 2003 evaluation was not applicable to current conditions.
 - a. What progress has EPA made in identifying and evaluating demand for IRIS toxicity assessments, and what report or study, if any, has EPA produced on current demand?

Answer: In June 2014, the IRIS Program began an agency-wide effort to determine program and regional office needs for current and future assessments (including the type of IRIS product

needed). The results of this survey will inform the next multi-year IRIS workplan. The IRIS workplan will enable the program to achieve a consistent and sustainable workflow that produces high-quality chemical assessments that are timely and responsive to agency needs. The IRIS Program anticipates making the new multi-year workplan publicly available as early as Fall 2014.

b. Given EPA's challenges in completing enough IRIS toxicity assessments to meet their annual goals (e.g., EPA completed 4 IRIS toxicity assessments in fiscal year 2012; falling short of its goal of completing 40 assessments for that year), how has EPA considered its current resource constraints when identifying how it will meet demand?

Answer: As noted above, EPA is conducting an evaluation of program and regional office needs for current and future IRIS assessments. Resource constraints will be considered as we develop the multi-year workplan and schedule for upcoming assessments from that survey. The survey of needs and the associated resource-loaded workplan provide agency planners with the information they need to ensure that appropriate resources are placed against the highest priority need.

EPA expects to complete more high quality IRIS assessments per year as a result of the July 2013, IRIS enhancements. Numerous assessments are at various stages of development, including public opportunities for discussion of chemical-specific assessment plans, literature searches and evidence tables, and draft assessments. In practice EPA expects that each assessment will take a shorter period of time to complete as significant science issues are better understood and are resolved earlier in the assessment development process.

4. According to data on EPA's website, 90% of the 560 completed IRIS assessments are more than 10 years old and 75% are more than 20 years old. However, over those intervening years, new data on many of these chemicals may have emerged, and certainly the methods for assessment have changed over these years (for example, as identified in EPA's 2005 Cancer guidelines). In 2009, EPA instituted a project to update older assessments, and the manager of that program (Dr. Chon Shoaf) was quoted as saying that the program would need to do 300 updates each decade just to keep from falling further behind. Has this program continued? In addition, organizations are urging the IRIS program to undertake assessments of yet additional chemicals not already on the list. What is the size of the current IRIS workload, and how do you propose to address it?

Answer: The IRIS Program has primarily focused on improving the assessment development process associated with its health assessments. These improvements have been geared towards addressing the NRC recommendations in 2011. As the focus has been on making substantial improvements to the process, the IRIS Program is only now beginning discussions on how to update older assessments. As these discussions continue, EPA will evaluate the potential options within the context of other agency needs identified by the multi-year workplan and other resource constraints. Since the July 2013 enhancements, the program has been actively

working on 21 assessments. This number includes 3 completed assessments (methanol (noncancer), biphenyl, 1.4-dioxane) and 18 that have gone to a public step as part of the IRIS Process. Additional assessments will be added over time to the existing workload in accordance with agency needs and in consideration of IRIS Program resources. The multi-year workplan will be instrumental in identifying priorities and scheduling assessments.

5. At the Committee's request, the EPA Inspector General issued a report last year on the use of the IRIS database by EPA program offices and regions. According to the IG's report, approximately "one-third (34 percent) of the survey respondents reported that they have used an alternate source for toxicity values when an IRIS value was available. The primary reason selected for using an alternate source was that the alternate source was more up-to-date with current scientific practice or information." Does it concern you that some of your colleagues at EPA don't use IRIS values and what will it take to fix this internal disconnect?

Answer: In the Office of Inspector General's report, 85 and 81 percent of respondents indicated that they used IRIS as their primary source of cancer and noncancer values, respectively. The IRIS Program believes this indicates that the values developed in IRIS assessments are of general utility to our program office and regional stakeholders. Thirty-four percent of the respondents indicated that they had experienced "a situation" in which they used an alternate source of toxicity values when an IRIS value was available; the primary reason for the use of an alternative source was because a more up-to-date value was available (68%). The agency is aware of the use of alternate sources of toxicity information and we believe that efforts to establish a multi-year workplan, as well as discussions to identify assessments that may have newer information, will ultimately reduce the frequency with which a program would feel the need to select a cancer or noncancer value from an alternative source of toxicity values.

6. In light of GAO's listing of IRIS on the "High Risk" list and the acknowledgement by EPA that it needs to both reform the program and produce/update more assessments, why did the President propose to reduce funding for the program in FY2015?

Answer: The agency is committed to effectively implementing its mission to protect public health and the environment, which depends on credible and timely assessments of the risks posed by chemicals. As such, we are committed to focusing resources on ensuring that the IRIS Program produces high quality assessments in a timely and transparent manner. Likewise, we are committed to continuing the development of high profile assessments of public health critical chemicals (such as inorganic arsenic, formaldehyde, hexavalent chromium, polychlorinated biphenyls, and ethylene oxide). The \$1.5M FY2015 budget reduction will affect primarily the development and timing of new assessments. It will not impact the development of the public health critical chemicals, which will be protected from budgetary impacts. The IRIS Program is also currently evaluating the chemical assessment demands across the Agency to address GAO's recommendations related to fully documenting the capacity needed to meet demands.

7. What is the projected cost of a typical IRIS assessment?

Answer: The resources required to complete IRIS assessments vary due to the size and complexity of the database underlying the toxicity of a given chemical. The cost of an IRIS assessment ranges from \$400,000 to \$2,500,000 in extramural funds and four to fifteen FTE's.

8. A common criticism of IRIS assessments is the tendency to be "public health protective," which can lead to unrealistically conservative assessments, which, in turn, can lead to overstated environmental risks and bad regulation. We have heard the oft-repeated mantra that IRIS assessments are purely scientific and not regulatory, but doesn't a bad risk assessment restrict a risk manager's options, ultimately forcing him or her to make a bad risk management decision?

Answer: IRIS assessments are intended to accurately and impartially reflect the science that details a chemical's toxicity. When critical information is lacking, IRIS assessments use approaches that help risk managers make decisions that are consistent with the agency's mission to protect human health and the environment. Ultimately, in the absence of data, the use of uncertainty factors and other "default" approaches is a valuable strategy to protect human health, including sensitive populations.

All the information included in an IRIS assessment, including the selection of modeling approaches and uncertainty factors, is reviewed by the Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC). A significant benefit of the SAB-CAAC is its independent review of the decisions made during development of the draft assessment.

A strong, scientifically rigorous IRIS Program is of critical importance and we are ensuring that IRIS assessments transparently and accurately address scientific issues and uncertainties, including the presentation of alternative analyses (e.g. modeling approaches) where appropriate. Presentation of alternative approaches in the supplemental information of an IRIS assessment informs risk managers and facilitates decision-making.

9. In 2009, you were part of a Bipartisan Policy Center report that unanimously recommended that "studies used in the formulation of regulation should be subject to data access requirements... regardless of who funded the study." Do you still agree with this statement? And how has this recommendation been implemented in the IRIS and National Ambient Air Quality Standard-setting process in your office?

Answer: Yes. This question addresses two important issues relevant to the development of IRIS assessments as well as the Integrated Science Assessments (ISA) that inform the development of the National Ambient Air Quality Standards: data access and funding source.

Transparency and scientific integrity are very important to the agency's work. Transparency is a critical element in EPA's Scientific Integrity Policy, which states, "To enhance transparency with the agency, this policy...facilitates the free flow of scientific information. The agency will continue to expand and promote access to scientific information by making it available online in open formats in a timely manner, including access to data and non-proprietary models underlying agency policy decisions." Both IRIS assessments and ISAs make information available about the

studies that inform the development of the documents through the Health Effects Research Online (HERO) database. Here, the general public can see information on the studies used in an assessment, primarily journal articles and technical reports, while adhering to distribution limitations due to copyright. Additionally, modeling code and output used in the development of an assessment is made available so that the public can see how decisions were made. The agency is currently exploring ways to make more of the underlying data available, acknowledging that in many cases, journal articles do not include the raw data supporting published results. In other cases, with human data, additional steps are essential to maintain the privacy of the personal health information of individuals who have participated in these studies.

With respect to funding source, all relevant, well-conducted, and peer-reviewed studies, regardless of funding source, and regardless of whether the results are positive or negative, are considered in the development of both IRIS assessments and the ISAs. In their 2014 review of the IRIS Process, the National Research Council (NRC) recommended that evidence evaluation and risk-of-bias analysis be conducted using methods that are "transparent, reproducible, and scientifically defensible." The NRC also recommended that funding sources be considered in systematic reviews conducted for IRIS assessments. Decisions made in IRIS assessments and ISAs continue to be based on the best available science. These topic will be discussed with systematic review experts and the public at an upcoming IRIS workshop to be held October 15-16, 2014.

10. While EPA often relies on scientific data produced by or funded by other government agencies in its assessments, those raw data are not made available to external reviewers and the public for independent evaluation. Stakeholders have tried many approaches to get these data through the Freedom of Information Act, but often come up short and if data are provided, it is not provided in a timely manner to help inform comments on the assessments. Will you ensure that all the data the IRIS program uses in its assessments are made accessible to all stakeholders (assuming appropriate privacy protections, etc...)?

Answer: EPA remains committed to transparency and scientific integrity, and the IRIS Program will continue to explore ways to increase access to the scientific information underlying its assessments. However, it is important to note that IRIS assessments typically rely on the "data" included in peer-reviewed journal articles, not the "raw data" underlying those publications and in the possession of the researcher(s). As such, the "data used in an assessment" is available in the assessment's references. In the rare cases where EPA obtains a researcher's dataset and reanalyzes the data for an IRIS assessment, the data is available when access to it is not restricted by applicable privacy requirements, confidential business claims, or similar restrictions via the IRIS website.

EPA's policy with respect to data will continue to be consistent with existing obligations to avoid disclosing material that may be confidential business information (as directed under the Trade Secrets Act and under OMB Circular A-130). In addition, the agency is committed to protecting citizens' privacy and preventing the release of personal information that could, directly or indirectly, be traced to specific individuals.

11. IRIS assessments routinely identify one or more reference values below which no bad effects in humans are expected, and these are provided to other EPA offices and other agencies as a guide for the establishment of regulations that often require control of the chemical down to the level the IRIS program has established. Several of the chemicals under the purview of the IRIS program, including methanol and formaldehyde, are produced naturally by the human body.

In the recent final assessment of methanol, your office published a reference level that, in the case of 20% of the U.S. population, is exceeded by that person's naturally-produced methanol and is also equal to the amount of methanol that is contained in just 25 ounces of orange juice.

a. Should EPA examine these kinds of naturally-occurring chemicals differently from other chemicals, perhaps by looking more closely at the safety margins that are built into these reference values and asking whether the resulting reference values are realistic? Do you have a plan to do so?

Answer: EPA is planning to convene a scientific workshop to discuss issues related to assessing the human health risks of exposure to environmental chemicals that are also produced in the body through normal biological processes (known as "endogenous chemicals"). IRIS assessments are developed to provide information on health effects associated with exposure to chemicals from sources over which EPA has regulatory authority, including some chemicals that occur naturally, either in the environment or are endogenously produced. The assessment of health risks associated with exposure to environmental chemicals that are also produced endogenously deserves careful consideration because there are many natural products of metabolism that can have toxic effects at high enough levels. The fact that they are naturally produced does not necessarily make them "safe" at all doses. The risk evaluated for a chemical is typically the risk of an increased effect beyond the effects observed in the "unexposed" group or population. IRIS values generally already take into account amounts commonly produced by our own bodies in how they are derived.

12. Could you tell us what an "adverse effect" means to you? Does EPA have any guidance on the definition of an "adverse effect," and does the IRIS program follow this guidance?

Answer: The IRIS Program adheres to the following definition of an adverse effect: "A biochemical change, functional impairment or pathologic lesion that affects the performance of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge." This definition is available online at: http://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists-search.do?details=&vocabName=IRIS%20Glossary.

13. To what extent does having multiple toxicity assessment sources for the same chemical present challenges for ensuring consistent risk management across the nation, and what steps has EPA taken to either minimize or explain reasons for any

differences?

Answer: EPA's IRIS Program is the only federal program devoted solely to the evaluation of health hazard and dose response information for the purposes of developing cancer and noncancer chronic toxicity values for the oral and inhalation pathways of exposure for the protection of public health. In addition, the IRIS Program qualitatively evaluates cancer information to ascertain human cancer potential. EPA's program and regional offices combine information from IRIS assessments with relevant exposure information for a chemical to assess the public health risks of environmental contaminants. EPA decision-makers use these risk assessments, along with other considerations (e.g., statutory/legal requirements that can include cost-benefit information, technological feasibility, and economic factors) to inform risk management decisions. The values derived by other federal health agencies are developed in response to different mandates and for different purposes. For example, the Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels (MRLs) are developed in response to a mandate under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), to provide toxicological profiles of hazardous substances found at National Priorities List sites. According to the ATSDR website (http://www.atsdr.cdc.gov/mrls/index.asp), these values are intended to serve as screening levels, and are used by ATSDR health assessors to identify contaminants and potential health effects that may be of concern at hazardous waste sites. ATSDR further states that "it is important to note that MRLs are not intended to define cleanup or action levels for ATSDR or other Agencies." EPA has a Memorandum of Understanding with ATSDR, working closely on some assessments to ensure our work in developing human health assessment is complementary and to share data and information on specific assessments. Within EPA, the Office of Solid Waste and Emergency Response has outlined a hierarchy of toxicity values to be used in making decisions at Superfund sites (http://www.epa.gov/oswer/riskassessment/pdf/hhmemo.pdf). This directive indicates that IRIS is the preferred choice of toxicity values in Superfund risk assessment activities, and it points to other sources of toxicity values, including those developed by ATSDR and California Environmental Protection Agency, that one can use in the event that an IRIS assessment is not available for a given chemical of concern.

- 14. Many of the well-known pollutants of concern apparently up for assessment revision by IRIS have been previously assessed by other federal health agencies-OSHA, the National Institute for Environmental Health Sciences, ATSDR, as well as other entities like the National Academy of Sciences, the World Health Organization, or the chemical industry.
 - a. What is particularly essential about the IRIS Assessment updates that justify this new batch of assessments? What health benefit might be gained?

Answer: As indicated above, EPA's IRIS Program is the only federal program devoted solely to the evaluation of health hazard and dose response information for the purposes of developing cancer and noncancer chronic toxicity values for the oral and inhalation pathways of exposure. In addition, the IRIS Program qualitatively evaluates cancer information to ascertain human cancer potential. Risk management issues, such as technical feasibility or limits of detection, which are sometimes considered in the development of toxicity values by other federal agencies, are developed separately from IRIS toxicity values. IRIS assessments are the scientific foundation

for EPA decisions to protect public health, and our primary clients are the program and regional offices who nominate chemicals for addition to the IRIS agenda. IRIS assessments undergo a very rigorous review process involving the public and stakeholders at various steps in the assessment development process, as well as internal agency scientists, scientists from other federal agencies, and rigorous independent external peer review. As indicated above, the values derived by other federal health agencies (e.g., ATSDR, NIOSH, OSHA) are developed in response to different mandates and for different purposes. For example, NIOSH acts under the authority of the Occupational Safety and Health Act of 1970 and develops Recommended Exposure Limits (RELs) for hazardous substances that are found in the workplace. RELs are intended to limit the concentration of the potential hazard in the workplace air to protect worker health. As stated on the NIOSH website

http://www.cdc.gov/niosh/topics/cancer/pdfs/1995_NIOSHRELpolicy.pdf), NIOSH RELs are based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques. OSHA's Permissible Exposure Limits (PELs) are issued in response to a mandate under the Occupational Safety and Health (OSH) Act of 1970. As stated on their website (https://www.osha.gov/dsg/topics/pel/), OSHA sets enforceable PELs to protect workers against the health effects from airborne exposure to hazardous substances. OSHA PELs are based on 8-hour exposures in the workplace. While values derived by other federal agencies may be appropriate for the workplace, for example, EPA's mandate is for public health which is a broader and, for vulnerable populations, a more complex undertaking.

b. What IRIS users/customers are calling for these new assessments?

Answer: IRIS assessments are the scientific foundation for EPA decisions to protect public health, and our primary clients are the program and regional offices who nominate chemicals for addition to the IRIS agenda. For example, IRIS is the first source of toxicity information used by the agency to make decisions and set cleanup levels.

c. Given that "science is science," why is an IRIS assessment superior to other assessments, including those of professional societies and industry?

Answer: The IRIS Program provides high quality, publicly available information on the toxicity of chemicals to which the public might be exposed. As indicated above, EPA's IRIS Program is the only federal program devoted solely to the evaluation of health hazard and dose response information for the purposes of developing cancer and noncancer chronic toxicity values for the oral and inhalation pathways of exposure. IRIS assessments undergo a very rigorous review process, involving the public and stakeholders at various steps in the assessment development process, as well as internal agency scientists, scientists from other federal agencies, and rigorous independent external peer review.

15. You have implemented a standing set of bi-monthly meetings to address chemical specific scientific issues as well as to have discussions about problem formulation. At the most recent June meeting, it appeared that many NGOs boycotted the meeting due to concerns they said were related to not knowing about the meetings and concerns regarding too much industry representation. It is our understanding that these meetings

have all been announced on the IRIS webpage, registration is open to everyone, and anyone who wishes to speak can get a slot on the agenda. Is this a fair representation of your actions to ensure that all representatives of the public are welcome to provide an input to the IRIS process, or do the arguments for the boycott have merit?

Answer: Yes—this is a fair representation of our actions to ensure the public has the opportunity to participate in our meetings. The IRIS Program welcomes anyone who is interested in participating or discussing scientific issues at our public meetings. We recognize that obtaining different perspectives on scientific issues is important, and for that reason, we have been exploring new mechanisms to invite scientists who might be interested in scientific topics to our meetings. We also recognize that not all of our stakeholders have the resources to travel to Washington, DC, to participate in a meeting. For the past year and a half, every public meeting held by the IRIS Program has also been available by webinar. This has been a successful model in that we often have 50-100 individuals participating by webinar from outside of Washington, DC. We are working to better ensure that webinar participants can more fully engage in our meetings, including encouraging webinar participants to actively participate in discussions remotely (i.e., via telephone). EPA also moderates these discussions to facilitate equal participation among both virtual and in-person attendees.

16. Should standard protocols be developed to enable all studies to be independently judged based on their quality, strength, and relevance, regardless of the author affiliation or funding source? If so, will you make development of these standard approaches a priority?

Answer: We have fully embraced the concepts of systematic review, and are committed to implementing the principles of systematic review in IRIS assessments as recommended by the NRC. The refinement of standard protocols to independently and transparently judge the quality and strength of a study identified through a literature search is a priority for the IRIS Program. In their 2014 review of the IRIS Process, the NRC recommended that evidence evaluation and risk-of-bias analysis be conducted using methods that are "transparent, reproducible, and scientifically defensible." The NRC also recommended that funding sources be considered in systematic reviews conducted for IRIS assessments. These topics will be discussed with systematic review experts and the public at an upcoming IRIS workshop on the 2014 NRC recommendations to be held October 15-16, 2014.

17. The science of hazard assessments has become complex in recent years. Does IRIS have the requisite staff and expertise in all the needed disciplines to draft assessments efficiently and quickly? Would a more qualified staff lead to more concise and accurate assessments, partially because much of the information in these 1,000+ page assessments could be climinated?

Answer: Yes, IRIS staff have expertise in the disciplines necessary to develop quality assessments quickly and efficiently. Aided by the 2013 enhancements to the IRIS process, the capacity of IRIS staff to draft assessments will benefit from increased upfront planning and early engagement with stakeholders and the public. The distribution of preliminary materials and early discussion of scientific issues will help IRIS staff better understand

differing viewpoints and allow for those issues to be better presented in draft assessments. Along with the public and stakeholder interaction that occurs at the bimonthly public science meetings, the IRIS Program is developing a means of augmenting the scientific expertise available during these public meetings with eminent scientific experts identified by the NRC. These individuals will help ensure scientific issues are properly and more fully addressed early in draft development.

18. Following up on our discussion in the hearing when you said you would get back to the Committee with specifics, do you anticipate the first couple of IRIS assessments that will incorporate all of the NRC recommendations to be on new chemicals, and if so, which ones, or will they be updates of old assessments?

Answer: I stated that it would be 3-5 years before we complete implementation of all the NRC recommendations. Given those timelines, we anticipate that the first assessments to fully incorporate all the NRC recommendations will be inorganic arsenic and formaldehyde.

19. How does EPA intend to approach more challenging IRIS reforms such as evidence integration and weight of evidence? When will EPA develop guidelines or integrate a consistent approach in actual assessments?

Answer: The IRIS Program is working toward developing standardized systematic review methods for selecting and evaluating studies as well as methodologies for evidence integration and weight-of-evidence determinations. To move forward in this area, in August 2013, the EPA convened a public scientific workshop focused on approaches for evaluating individual studies, synthesizing evidence within a particular discipline, and integrating evidence across different disciplines to draw scientific conclusions and causality determinations. Another workshop will be held on October 15-16, 2014, to discuss systematic integration of evidence streams from human, animal, and mechanistic studies, as recommended by the NRC in their 2014 review of the IRIS process.

Also in 2013, the IRIS Program began development of a handbook to describe standard protocols and processes for staff to use when developing an IRIS assessment. This draft handbook represented our initial thoughts on several topics relevant to systematic review, including evidence integration and evaluating the evidence for a given effect. The draft handbook was provided to the NRC committee reviewing the IRIS process to inform their deliberations. The NRC noted in the 2014 report that elements of the draft handbook address many of the concerns over evidence evaluation raised by the NRC formaldehyde report. At the same time, the NRC encouraged further development and completion of the handbook as the IRIS program identifies best practices that facilitate the application of systematic review to IRIS assessments. Development of the draft handbook is ongoing.

The IRIS Program is continuing to evolve and the more challenging reforms noted above are under active consideration by the program. The 2014 NRC report commended the agency's efforts to improve the IRIS Program, and that the program had made substantial progress in the short time since release of the formaldehyde report. The IRIS Program anticipates that

completion of the recommendations presented in the 2011 and 2014 reports, including those on evidence integration, will be completed in three to five years.

- 20. The testimony from Mr. Walls noted that even though EPA documents are peer reviewed, the EPA staff that write the assessments are judge and jury of which comments from the public and from peer review experts are accepted and rejected. In fact, it was brought to our attention that in the recently finalized methanol document, EPA staff used the response to comments to describe a new policy position and approach to address endogenous exposures.
 - a. Do you support such actions? Should there be an independent entity, similar to the role a journal editor plays, to review how EPA staff respond to comments before the document is finalized?

Answer: Public comment and robust expert peer review is an important part of the agency's scientific work, and responding to public and peer review comments is an important step in completing a scientific product. It is not our intention to incorporate new policy positions in responses to comments. A core value of the IRIS Program is to appropriately address comments received from the public and external peer review. Following external peer review, EPA revises draft IRIS assessments to respond to public and peer review comments. The revised draft assessment is then reviewed by agency scientists who do not work in the IRIS Program; additionally, it is reviewed by scientists from other federal agencies and the Executive Office of the President. Each IRIS assessment documents the responses to public and peer review comments in an appendix that is publicly available. With the 2013 IRIS enhancements, EPA established a new Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC). The CAAC will provide independent review of IRIS assessments. A significant benefit to the IRIS Program from the standing SAB panel is the continuity it will provide across multiple assessments, and the capability to ensure that peer review comments across assessments are similarly and adequately addressed.

21. The National Research Council recommends that the IRIS handbook be peer reviewed. Has this happened? Will it? If so, when, and if not, why not?

Answer: No, the IRIS handbook has not yet been peer reviewed because it is still under development as we consider the recommendations of the NRC's 2014 report, and consider forthcoming discussions on their recommendations at the upcoming October 15-16 IRIS workshop. The handbook will be peer reviewed in the future, but the form of the peer-review may vary depending on how the handbook is developed. The handbook is considered to be an evolving, "evergreen" document that will be updated to incorporate new approaches when the IRIS Program identifies best practices in applying systematic review to IRIS assessments. At this time, we anticipate that as parts of the handbook are completed and implemented in the development of a given chemical assessment, they will be sent for peer reviewed. Portions of the handbook may also be discussed at IRIS bimonthly public science meetings to gather additional feedback.

- 22. You have recently developed a subpanel of the EPA Science Advisory Board to review IRIS assessments.
 - a. Will this panel be asked to review cross-cutting issues, like assessments of chemicals below background or endogenous exposures?

Answer: Yes the CAAC will be consulted on cross-cutting scientific issues in the course of their assessment reviews.

a. Will you take public comment on the "charge questions" asked of this panel?

Answer: Yes. As part of the IRIS enhancements, in step 4 of the IRIS process, the draft assessment and a draft of the peer review charge are released for public comment and discussion at an IRIS public science meeting. The draft charge or assessment may be revised prior to being released to peer review in order to be responsive to public comments.

c. Consistent with the Environmental Research, Development, and Demonstration Authorization Act, which authorizes the Science Advisory Board, will you allow this panel to answer any and all questions sent by this Committee?

Answer: The SAB is a federal advisory committee established by the EPA Administrator and, as with all EPA federal advisory committees, is subject to "administrative guidelines and management controls" established by the EPA Administrator. (See, FACA section 8(a)). As required by FACA, the EPA Designated Federal Official calls each meeting and approves the agenda for each meeting.

EPA and staff of the House Science, Space and Technology committee are developing a process for managing questions on which the specific congressional committees would like SAB advice.

23. The National Research Council recommends that EPA should provide technical assistance to stakeholders who don't have resources to provide input. How is EPA implementing or planning to implement this proposal fairly so that one class of stakeholders isn't overly assisted?

Answer: In the 2014 NRC review of the IRIS process, the committees commended our initiatives to engage with stakeholders and the public, while noting that differences in scientific and financial resources may contribute to an imbalance in public input to the IRIS Program. The IRIS Program already conducts significant outreach activities to ensure that potential stakeholders are made aware of upcoming IRIS activities. These activities include the use of webinars to expand access to individuals unable to travel to the D.C. area; email and social media, particularly to professional societies and disease interest groups; and IRIS

and Human Health Risk Assessment program bulletins that are sent to several thousand individuals. Reaching out through a variety of methods broadens the array of stakeholders and helps to ensure that no one group of stakeholders is uninformed.

Additionally, the IRIS Program is developing a proposal by which technical assistance can be provided through the National Research Council. The intent of this proposal is to engage the NRC to identify, evaluate, and arrange for scientific experts to participate in IRIS public meetings. The primary benefits of this arrangement are that it is expected to improve access to subject matter experts and provide a wider range of scientific perspectives. Individuals participating through this NRC augmentation of the IRIS public science meetings will not represent any specific group of stakeholders, but their presence will enhance and focus public discussion on key scientific issues. The IRIS Program anticipates that access to these subject matter experts early in the assessment development process will also enhance the quality of IRIS assessments.

AL-14-001-4401

PETER J. VISCLOSKY
1ST DISTRICT, INDIANA

COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEES:
RANKING MEMBER, DEFENSE
ENERGY AND WATER DEVELOPMENT

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INTERNET: http://visclosky.house.gov

August 21, 2014

The Honorable Gina McCarthy Administrator Enivronmental Protection Agency 1200 Pennsylvania Avenue Northwest Washington, D.C. 20460

Dear Administrator McCarthy:

I write on behalf of exempt 6, a resident of Indiana's First Congressional District.

chemical spraying conducted by planes in Northwest Indiana. Specifically, he would like to know if the Environmental Protection Agency (EPA) is aware of planes spraying chemicals into the air while in flight, including in Northwest Indiana. If planes are spraying chemicals while in flight, would like to know if those chemicals pose an environmental or health threat and if it is possible for the EPA to test the air in Northwest Indiana for chemicals. I would appreciate your addressing his concerns.

Thank you in advance for your serious consideration of this matter. Do not hesitate to let me know if you have any other questions or need additional information.

Sincerely,

Peter J. Visclosky Member of Congress

PJV:ma Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 1 6 2014

OFFICE OF AIR AND RADIATION

The Honorable Peter J. Visclosky U.S. House of Representatives Washington, D.C. 20515

Dear Congressman Visclosky:

Thank you for your latter of Aponet 21, 2014, to the U.S. Environmental Protection Agency on behalf of your constituent, . ** **Ultimate of the concerns regarding the potential practice of chemical spraying conducted by planes in Northwest Indiana. The Administrator asked that I respond on her behalf.

The EPA is not aware of any deliberate actions to release chemical or biological agents into the atmosphere. It is likely observing contrails, which are line-shaped clouds or "condensation trails" composed of ice particles that are visible behind jet aircraft engines under certain atmospheric conditions.

Jet aircraft engines operating at high altitudes emit tiny combustion-related particles, and water vapor present in the ambient atmosphere reacts with these particles to form contrails. Contrails are about 99 percent frozen water vapor and less than one percent combustion-related particles. These contrails spread due to atmospheric turbulence and sometimes join with other contrails and expand into large, natural-looking clouds that can cover large areas of the sky. Persistent contrails can last for hours while growing to several kilometers in width and 200 to 400 meters in height.

Aircraft emission standards for gas turbine engines that power civil aircraft have been in place for about 30 years. The EPA sets the emission standards for the engines, and the Federal Aviation Administration enforces the standards. Emission standards apply to essentially all commercial aircraft and address smoke, unburned hydrocarbons, carbon monoxide, and oxides of nitrogen (NOx) for the landing and takeoff cycle. Enclosed are documents entitled "Aircraft Contrails Factsheet" and "Contrails Facts." A 1999 report entitled, "Aviation and the Global Atmosphere," can be accessed at www.cambridge.org. Additional information about these documents is also enclosed.

Again, thank you for your letter. If you have further questions, please contact me or your staff may contact Cheryl Mackay in the EPA's Office of Congressional and Intergovernmental Relations at mackay.cheryl@epa.gov or (202) 564-2023.

Sincerely,

Janet G. McCabe

Acting Assistant Administrator

1.0 B. M.CL

Enclosures



Aircraft Contrails Factsheet

Summary

his fact sheet describes the formation, occurrence, and effects of "condensation trails" or "contrails." It was developed by scientific and regulatory experts at the Environmental Protection Agency (EPA), the Federal Aviation Administration (FAA), the National Aeronautics and Space Administration (NASA), and the National Oceanic and Atmospheric Administration (NOAA) in response to public inquiries regarding aircraft contrails. Contrails are line-shaped clouds sometimes produced by aircraft engine exhaust, typically at aircraft cruise altitudes several miles above the Earth's surface. The combination of water vapor in aircraft engine exhaust and the low ambient temperatures that often exists at these high altitudes allows the formation of contrails. Contrails are composed primarily of water (in the form of ice crystals) and do not pose health risks to humans. They do affect the cloudiness of the Earth's atmosphere, however, and therefore might affect atmospheric temperature and climate. The basic processes of contrail formation described in this fact sheet apply to both civil and military aircraft.



What are contrails?

ontrails are line-shaped clouds or "condensation trails," composed of ice particles, that are visible behind jet aircraft engines, typically at cruise altitudes in the upper atmosphere. Contrails have been a normal effect of jet aviation since its earliest days.

Depending on the temperature and the amount of moisture in the air at the aircraft altitude, contrails evaporate quickly (if the humidity is low) or persist and grow (if the humidity is high). Jet engine exhaust provides only a small portion of the water that forms ice in persistent contrails. Persistent contrails are mainly composed of water naturally present along the aircraft flight path.



How are aircraft emissions linked to contrail formation?



ircrast engines emit water vapor, carbon dioxide (CO₂), small amounts of nitrogen oxides (NO_x), hydrocarbons, carbon monoxide, sulfur gases, and soot and metal particles formed by the high-temperature combustion of jet suel during slight. Of these emittants, only water vapor is necessary for contrail formation. Sulfur gases are also of potential interest because they lead to the formation of small particles. Particles suitable for water droplet formation are necessary for contrail formation. Initial contrail particles, however, can either be already present in the atmosphere or formed in the exhaust gas. All other engine emissions are considered nonessential to contrail formation.



¹This fact sheet focuses on contrails produced by aircraft engine exhaust. However, the term "contrail" is also used to refer to the short trails sometimes briefly appearing over aircraft wings or engine propellers, especially under mild, humid conditions. These contrails consist entirely of atmospheric water that condenses as a result of local reductions in pressure due to the movement of the wing or propeller.



Figure 1. Contrails forming behind the engines of a Lufthansa Airbus A310-330 cruising at an altitude of 35,100 ft (10.7 km) as seen from research aircraft. (Photo:German Aerospace Center (Deutsches Zentrum für Luft- und Raumfahrt (DLR)), Oberpfaffenhofen, Germany.) Inset: Contrails forming behind the engines of a large commercial aircraft. Typically, contrails become visible within roughly a wingspan distance behind the aircraft. (Photo: Masako Imai, Cloud Castle/Photo Sky Japan.)

How do contrails form?

or a contrail to form, suitable conditions must occur immediately behind a jet engine in the expanding engine exhaust plume. A contrail will form if, as exhaust gases cool and mix with surrounding air, the humidity becomes high enough (or, equivalently, the air temperature becomes low enough) for liquid water condensation to occur. The level of humidity reached depends on the amount of water present in the surrounding air, the temperature of the surrounding air, and the amount of water and heat emitted in the exhaust.

Atmospheric temperature and humidity at any given location undergo natural daily and seasonal variations and hence, are not always suitable for the formation of contrails.

If sufficient humidity occurs in the exhaust plume, water condenses on particles to form liquid droplets. As the exhaust air cools due to mixing with the cold local air, the newly formed droplets rapidly freeze and form ice particles that make up a contrail (See Figure 1). Thus, the surrounding atmosphere's conditions determine to a large extent whether or not a contrail will form after an aircraft's passage. Because the basic processes are very well understood, contrail formation for a given aircraft flight can be accurately predicted if atmospheric temperature and humidity conditions are known.

After the initial formation of ice, a contrail evolves in one of two ways, again depending on the surrounding atmosphere's humidity. If the humidity is low (below the conditions for ice condensation to occur), the contrail will be short-lived. Newly formed ice particles will quickly evaporate as exhaust gases are completely mixed into the surrounding atmosphere. The resulting line-shaped contrail will extend only a short distance behind the aircraft (See Figure 2).

If the humidity is high (greater than that needed for ice condensation to occur), the contrail will be persistent. Newly formed ice particles will continue to grow in size by taking water from the surrounding atmosphere. The resulting line-shaped contrail extends for large distances behind an aircraft (See Figures 2 and 3). Persistent contrails can last for hours while growing to several kilometers in width and 200 to 400 meters in height. Contrails spread because of air turbulence created by the passage of aircraft, differences in wind speed along the flight track, and possibly through effects of solar heating.

What are the ingredients of jet fuel, and are they important to contrail formation?

Il jet fuel is a hydrocarbon mixture containing small amounts of impurities and additives. All aircraft jet fuel is analyzed for strict impurity limits before use. The hydrocarbon content of jet fuel produces water vapor as a by-product of combustion. Contrails would not form behind aircraft engines without the water vapor by-product present in exhaust.

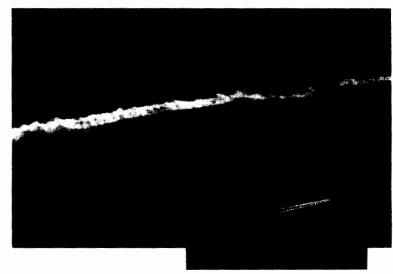


Figure 2. Photograph of two contrail types. The contrail extending across the image is an evolving persistent contrail. Shown just above it is a short-lived contrail. Short-lived contrails evaporate soon after being formed due to low atmospheric humidity conditions. The persistent contrail shown here was formed at a lower altitude where higher humidity was present Inset: Another example of a short-lived contrail. (Photos: J. Holecek, NOAA Aeronomy Laboratory, Boulder, CO.)



Figure 3. Persistent contrails and contrails evolving and spreading into cirrus clouds. Here, the humidity of the atmosphere is high, and the contrail ice particles continue to grow by taking up water from the surrounding atmosphere. These contrails extend for large distances and may last for hours. On other days when atmospheric humidity is lower, the same aircraft passages might have left few or even no contrails. (Photo: L. Chang, Office of Atmospheric Programs, U.S. EPA.)

weight), which contributes to the formation of small particles containing various sulfur species. These particles can serve as sites for water droplet growth in the exhaust and, if water droplets form, they might freeze to form ice

fuel is sulfur (~0.05% by

particles that compose a contrail. Enough particles are present in the surrounding atmosphere, however, that particles from the engine are not required for contrail formation. There are no lead or ethylene dibromide additives in jet fuel. Additives currently used in jet fuels are all organic compounds that may also contain a small fraction of sulfur or nitrogen.

Why are persistent contrails of interest to scientists?

ersistent contrails are of interest to scientists because they increase the cloudiness of the atmosphere. The increase happens in two ways. First, persistent contrails are line-shaped clouds that would not have formed in the atmosphere without the passage of an aircraft. Secondly, persistent contrails often evolve and spread into extensive cirrus cloud cover that is indistinguishable from naturally occurring cloudiness (See Figure 3). At present, it is unknown how much of this more extensive cloudiness would have occurred without the passage of an aircraft. Not enough is known about how natural clouds form in the atmosphere to answer this question.

Changes in cloudiness are important because clouds help control the temperature of the Earth's atmosphere. Changes in cloudiness resulting from human activities are important because they might contribute to long-term changes in the Earth's climate. Many other human activities also have the potential of contributing to climate change. Our climate involves important parameters such as air temperature, weather patterns, and rainfall. Changes in climate may have important impacts on natural resources and human health. Contrails' possible climate effects are one component of aviation's expected

overall climate effect. Another key component is carbon dioxide (CO2) emissions from the combustion of jet fuel. Increases in CO2 and other "greenhouse gases" are expected to warm the lower atmosphere and Earth's surface. Aviation's overall potential for influ-

encing climate was recently assessed to be approximately 3.5 percent of the potential from all human activities (See Box 1).

Persistent line-shaped contrails are estimated to cover, on average, about 0.1 percent of the Earth's surface (Sausen et al., 1998; see Figure 4). The estimate uses:

- · meteorological analysis of atmospheric humidity to specify the global cover of air masses that are sufficiently humid (low enough atmospheric temperature) for persistent contrails to form
- data from 1992 reported aircraft operations to specify when and where aircraft fly
- · an estimated average for aircraft engine characteristics that affect contrail formation
- · satellite images of certain regions of the Earth in which contrail cover can be accurately measured (See Figure 5)

The highest percentages of cover occur in regions with the highest volume of air traffic, namely over Europe and the United

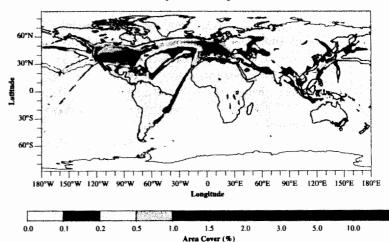


Figure 4. Estimated global persistent contrail coverage (in percent area cover) for the 1992 worldwide aviation fleet. The global mean cover is 0.1 percent. See text for description of how this estimate was made. (Reproduced with permission from Sausen et al., 1998, Figure 3, left panel.)

States (See Figure 4). This estimate of contrail cloudiness cover does not include extensive cirrus cloudiness that often evolves from persistent line-shaped contrails. Some evidence suggests that this additional cirrus cloudiness might actually exceed that of line-shaped cloudiness.

How is contrail coverage expected to change in the future?

ontrail cover is expected to change in the future if changes occur in key factors that affect contrail formation and evolution. These key factors include aircraft engine technologies that affect emissions and conditions in the exhaust plume; amounts and locations of air traffic; and background atmospheric humidity conditions. Changes in engine fuel efficiency, for example, might change the amount of heat and water emitted in the exhaust plume, thereby affecting the frequency and geographical cover of contrails. Changes in air

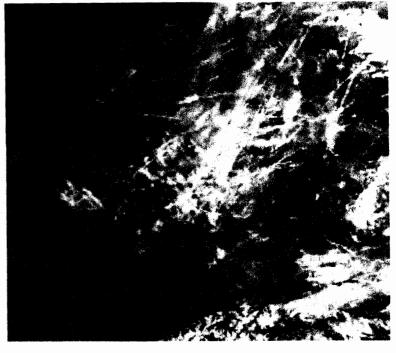


Figure 5. Satellite photograph showing an example of contrails covering central Europe on May 4, 1995. The average cover in a photograph is estimated by using a computer to recognize and measure individual contrails over geographical regions of known size. Photograph from the National Oceanic and Atmospheric Administration (NOAA)-12 AVHRR satellite and processed by DLR (adapted from Mannstein et al., 1999). (Reproduced with permission of DLR.)

traffic might also affect persistent contrail formation. It is currently estimated that regions of the atmosphere with sufficient humidity to support the formation of persistent contrails cover about 16 percent of the Earth's surface. If air traffic in these regions increases in the future, persistent line-shaped contrail

BOX 1



Scientific Assessment of the Global Atmospheric Effects of Aviation



The Intergovernmental Panel on Climate Change (IPCC) was established by the World Meteorological Organisation (WMO) and the United Nations Environment Programme (UNEP) in 1988 to assess the science, technology, and socioeconomic information needed to understand the risk of human-induced climate change. The 1999 IPCC report, "Aviation and the Global Atmosphere," (see References) describes current knowledge regarding aircraft effects on the global atmosphere. The report was compiled by more than 100 authors from 18 countries. Technical experts from the aviation industry, including airlines and airframe and engine manufacturers, worked with atmospheric scientists in creating this report.

The report considers all gases and particles emitted by aircraft into the upper atmosphere. It also examines the

role these gases and particles play in modifying the atmosphere's chemical properties and initiating the formation of contrails and cirrus clouds. Chapter 3 of the IPCC report provides detailed information about contrail formation, occurrence, and persistence. The report also considers how potential changes in aircraft technology; air transport operations; and the institutional, regulatory, and economic framework might affect emissions in the future. It does not address the effects of engine emissions on local air quality near the surface or potential human health effects of engine emissions. The report notes that significant scientific uncertainty is associated with aviation's predicted influence on climate. A report summary is available from the IPCC Web site at <www.ipcc.ch>.

cover there will also increase. Overall, based on analysis of current meteorological data and on assumptions about future air traffic growth and technological advances, persistent contrail cover is expected to increase between now and the year 2050.

Are persistent contrails harmful to the public?

ersistent contrails pose no direct threat to public health.
All contrails are line-shaped clouds composed of ice particles. These ice particles evaporate when local atmospheric conditions become dry enough (low enough relative humidity). The ice particles in contrails do not reach the Earth's surface because they fall slowly and conditions in the lower atmosphere cause ice particles to evaporate.

Contrail cloudiness might contribute to human-induced climate change. Climate change may have important impacts on public health and environmental protection.

Do authorities regulate aircraft emissions?

n the United States, some aspects of aviation emissions are regulated through the efforts of several government agencies. The U.S. Environmental Protection Agency (EPA), under the Clean Air Act (CAA) of 1970, has established commercial aircraft engine exhaust emissions standards for certain emittants associated with ground-level air pollution. Jet engine exhaust contains, among other emittants, oxides of nitrogen (NOx) and hydrocarbons that contribute to ozone formation. Jet aircraft are one of many sources of these pollutants. Ozone is a prime ingredient of smog in and near cities and other areas of the country. While EPA establishes emissions standards for aircraft, the Federal Aviation Administration (FAA) of the U.S. Department of Transportation (DOT) administers and enforces these standards. This domestic framework for regulating aircraft engine emissions is more fully described in Box 2. Currently, there are no regulations addressing contrails and their atmospheric effects.



U.S. Environmental Regulatory Framework for Aircraft Engine Emissions

The Clean Air Act (CAA) directs the U.S. Environmental Protection Agency (EPA) to establish aircraft and aircraft engine emissions standards for any air pollutant that could reasonably endanger public health and welfare. In 1997, EPA aligned U.S. emissions standards (40 CFR Part 87) with engine emissions standards and recommended practices (SARPs) prescribed by the International Civil Aviation Organization (ICAO), a United Nations agency established in 1944 that develops SARPs using the technical support of member states and the aviation community. The United States is an active member of ICAO's Committee on Aviation Environmental Protection, which is responsible for further development of engine emissions standards. In establishing U.S. emissions standards, EPA must consult with the Department of Transportation (DOT) to ensure such regulations' effective dates permit the development

of requisite technology, giving appropriate consideration to compliance cost. It must also consult with DOT concerning aircraft safety before promulgating emissions standards.

Under the CAA, DOT is responsible for enforcing standards established by EPA. DOT delegated enforcement responsibility to the Federal Aviation Administration (FAA). FAA has issued regulations administering and enforcing the emissions standards that apply to civil airplanes powered by gas turbine engines. FAA ensures compliance with these regulations by reviewing and approving certification test plans, procedures, test reports, and engine emissions certification levels. For more information on aircraft emissions or to access EPA's or FAA's aircraft regulations, visit the Aviation Emissions Website of EPA's Office of Transportation and Air Quality at <www.epa.gov/otaq/aviation.htm>.

For further information

urther scientific information about the effects of aircraft on the upper atmosphere can be found in the 1999 IPCC report, "Aviation and the Global Atmosphere" (see References). Information about aircraft and aircraft engine emissions regulations can be found at EPA's aviation emissions Web site, <www.epa.gov/otaq/aviation.htm>. Information about military aircraft and military space launch activities, and their atmospheric and environmental effects, can be found at http://xre604.brooks.af.mil/safmiq/esoh_issues.htm>. For additional copies or further information on this fact sheet, contact the EPA Stratospheric Protection Hotline at 800 296-1996.

Note: Some images or photos in this fact sheet were provided courtesy of other institutions or parties and may be protected by copyright. Permissions regarding those photos or images need to be obtained from the indicated source.





References

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Mannstein, H., R. Meyer, and P. Wendling, 1999. Operational detection of contrails from NOAA-AVHRR data. *Int. J. Remote Sensing*, 20, 1641-1660.





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Environmental Protection Agency (6205J)
Ariel Rios Building
1200 Pennsylvania Avenue, NW.
Washington, DC 20460



CONTRAILS FACTS

The Air Force operates many aircraft and space systems that are constantly interacting with the environment. Atmospheric interactions such as exhaust gases forming contrails, chaff and flares deployment that produce smoke, aerial pest or weed control spraying, or in-flight emergency fuel releases usually have very minor environmental impacts over a very limited geographical area. This site provides basic information and links about contrails, aircraft and space launch exhaust emissions, chaff and flares, aerial spraying, in-flight emergency procedures, and related topics.

Aircraft, engines, chaff, and flares can produce a variety of condensation patterns (or contrails), exhaust plumes, vapor trails, or smoke patterns. The exhaust emissions produced by aircraft and space launch vehicles can produce contrails that look very similar to clouds which can last for only a few seconds or as long as several hours. Vapor trails are formed only under certain atmospheric conditions and create a visible atmospheric wake similar to a boat propeller in water and usually dissipate very rapidly. Chaff and flares produce unique smoke patterns that are visibly different than a contrail but have the same color and appearance as a cloud but which also typically dissipates very quickly. Aerial spraying for pest or weed control and fire suppression are the only Air Force activities which involve aircraft intentionally spraying chemical compounds (insecticides, herbicides, fire retardants, oil dispersants). In the case of an in-flight emergency, jet fuel may be released to lighten the landing weight and minimize the risk of fire if the aircraft should crash.

Background

The US military has played a significant historical role in the development of aircraft and space launch vehicles, airspace management, environmental management, and public land management procedures. In the earliest years of aviation and rocketry and up through the late 1980s, the military owned and operated the majority of the United States aircraft and space launch fleets. Since the end of the 1991 Persian Gulf War, the USAF has been in a drawdown and restructuring mode. In 1990, there were approximately 9,059 aircraft in the Air Force inventory and approximately 6,126 aircraft in 2000. Of the approximately 6,228 aircraft in the USAF fleet in 1998, 4,447 were assigned to active duty Air Force installations and 1,781 were assigned to Guard and Reserve units, usually co-located at municipal airports. For a more detailed discussion on the changing nature of military and civilian aviation, see A Review Of Military Aviation And Space Issues at http://www.felsef.org/dec99.htm.



In the 1980s, commercial airline passenger service and satellite telecommunication growth resulted in an increase in civil aircraft and space booster fleets with numbers almost equivalent to the military (total of all services). Future projections for the next 15 years indicate that commercial aviation and space launch fleets will become larger than the military fleet.

The civil aviation fleet is projected to grow from 12,281 aircraft in 1997 to 25,998 in 2017. The assumptions on growth rates and types of

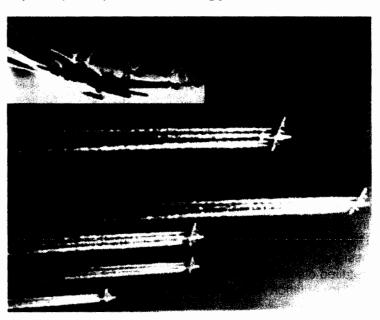
aircraft are dependent on many changes in air traffic control, airspace management, and economic growth, but the general trend for civil aviation is increasing capacity by adding more frequent flights with smaller regional jets.

Aircraft fly along specific routes and corridors called the National Airspace System (NAS). The NAS is comprised of the air navigation routes and infrastructure across the United States that supports approximately 60,000 daily flights of commercial, general aviation, and military flights. The FAA is the lead federal agency charged with the operations and maintenance of the NAS. They manage over 5-million square miles of land routes and 23-million square miles of oceanic routes. The FAA must balance the safety and efficiency of the NAS on a daily basis. Many agencies and organizations are involved with the National Airspace System for a variety of purposes: civil air carriers, general aviation, military services, and research organizations. A typical snapshot of daily aircraft operations in the United States is shown below.

In the last ten years, there has been tremendous growth in the number of aircraft operated around the world. The majority of aircraft seen overhead are civilian flights, particularly near large cities. For a more detailed description of the NAS, see A Review Of Military Aviation And Space Issues: Aerospace And Airspace (Part II) at http://www.felsef.org/jan00.htm.

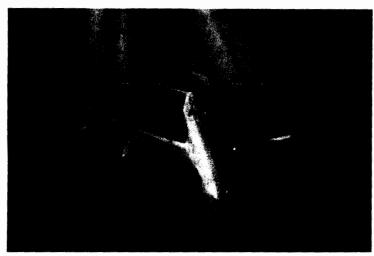
Condensation Trails ("contrails") from Aircraft Engine Exhaust

Contrails (short for "condensation trails") are line-shaped clouds sometimes produced by aircraft engine exhaust. The combination of high humidity and low temperatures that often exists at aircraft cruise altitudes allows the formation of contrails. Contrails are composed primarily of water (in the form of ice crystals) and do not pose health risks to humans. Contrails have been a normal effect of aviation since its earliest days. Depending on the temperature and the amount of moisture in the air at the aircraft altitude, contrails can either



evaporate quickly or they can persist and grow. Engine exhaust produces only a small portion of the water that forms ice in persistent contrails. Persistent contrails are mainly composed of water naturally present along the aircraft flight path.

Aircraft engines emit water vapor, carbon dioxide (CO2), small amounts of nitrogen oxides (NOx), hydrocarbons, carbon monoxide, sulfur gases, and soot and metal particles formed by the high-temperature combustion of jet fuel during flight. Of these emittants, only water vapor is necessary for contrail formation. Sulfur gases are also of potential interest because they lead to the formation of small particles. Particles suitable for water droplet formation are necessary for contrail formation. Initial contrail particles, however, can either be already present in the atmosphere or formed in the exhaust gas. All other engine emissions are considered nonessential to contrail formation.



For a contrail to form, suitable conditions must occur immediately behind a jet engine in the expanding engine exhaust plume. A contrail will form if, as the exhaust gases cool and mix with surrounding air, the humidity becomes high enough (or, equivalently, the air temperature becomes low enough) for liquid water to condense on particles and form liquid droplets. If the local air is cold enough, these newly formed droplets then freeze and form ice particles that make up a contrail. Because the basic processes are

very well understood, contrail formation for a given aircraft flight can be accurately predicted if atmospheric temperature and humidity conditions are known.

After the initial formation of ice, a contrail evolves in one of two ways. If the humidity is low, the contrail will be short-lived. Newly formed ice particles will quickly evaporate. The resulting contrail will extend only a short distance behind the aircraft. If the humidity is high, the contrail will be persistent. Newly formed ice particles will continue to grow in size by taking water from the surrounding atmosphere. The resulting lineshaped contrail extends for large distances behind an aircraft. Persistent contrails can last for hours while growing to several kilometers in width and 200 to 400 meters in height. Contrails spread because of air turbulence created by the passage of aircraft, differences in wind speed along the flight track, and possibly through effects of solar heating.

Thus, the surrounding atmosphere's conditions determine to a large extent whether or not a contrail will form after an aircraft's passage, and how it evolves. Other factors that influence contrail formation include engine fuel efficiency, which affects the amount of heat and water emitted in the exhaust plume.



Contrails become visible roughly about a wingspan distance behind the aircraft. Contrails can be formed by propeller or jet turbine powered aircraft. During WWII, large formations of bombers left strikingly remarkable contrail formations. Typical contrails are shown below.

The contrails formed by the exhaust at high altitude are typically white and very similar to cirrus clouds. As the exhaust gases expand and mix with the atmosphere, the contrail diffuses and spreads. It is very difficult to distinguish aged contrails from cirrus clouds. It is very difficult to distinguish aged contrails from cirrus clouds. At sunsets, these contrails can be visibly eyecatching and striking as they reflect the blue, yellow, and red spectrum of the reflected sunlight.



Persistent contrails are of interest to scientists because they affect the cloudiness of the atmosphere. Scientists in the United States. Europe, and elsewhere have studied contrail formation, occurrence, and persistence, and research efforts on these topics continue. Shown below is a photo taken from the research aircraft Falcon of the German Aerospace Center (Deutsches Zentrum fh r Luft- und Raumfahrt (DLR) at about flight level 33,300 feet of an Airbus A340 with contrails (left) and a Boeing 707 without contrails (right). This illustrates a scientific effort to evaluate the effects of different engine characteristics on contrail formation.

The Air Force uses a Boeing 707 airframe for the KC-135 refueling and E-3 AWACS aircraft. The KC-135 fleet is in the process of upgrading to newer engines which produce fewer emissions and noise. Scientific research on contrails was recently summarized by an international group of experts. This summary can be found in Chapter 3 of the report, "Aviation and the Global Atmosphere," published in 1999 by Cambridge University Press for the Intergovernmental Panel on Climate Change (IPCC). The report describes current knowledge regarding the effects of aircraft emissions on the global atmosphere. The full report is available from Cambridge University Press and a summary of this report is at www.ipcc.ch.

Wingtip Condensation Trails



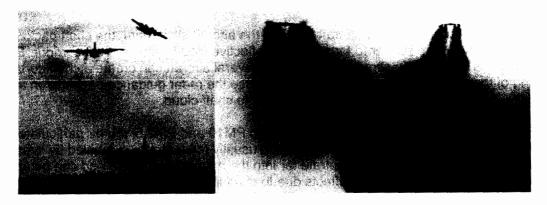
A different type of contrail or condensation trail is caused when a wing surface or winglet causes a cavitation of air in very humid conditions. This results in a unique vapor trail that is not formed due to exhaust gases. The next time you fly in a commercial aircraft through a rain cloud, look for the vapor trails that form over and around the wing. Typical fighter wingtip contrails are shown below.

Exhaust Gases and Emissions

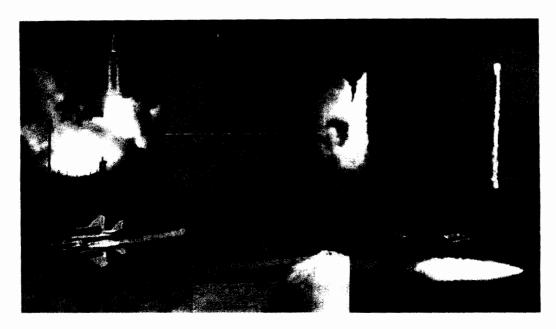
Often, military aircraft can be seen taking off with a black smoke appearing from the engines. This smoke is mainly soot particles, similar to diesel engines. Commercial aircraft also produce the same type of soot particles, but usually not to the same degree as military aircraft. This is for two reasons: the type of fuel and the type of engines.

Most military aircraft use JP-8 jet fuel which is a blend of commercial Jet Aviation Fuel -1 (or Jet A-1) with three extra additives. The additives are used to control ice formation, control biogrowth (molds and slimes), and inhibit corrosion. The military uses these additives because of the unique environments the military operates in, the type of self-sealing fuel tanks used, and the type of metals, plastics, and sealant used on military aircraft. Several specialized aircraft like the SR-71 and U-2 use different fuels than JP-8, but are developed from the same base stock. Fuels research is always ongoing. The newest fuel being brought into production is JP-8+100. Dubbed JP-8+100 because the additive package can increase the thermal stability of military fuel by 100 degrees Fahrenheit, the improved fuel helps prevent gums and deposits that can foul fuel lines.

Military engines are also designed with different performance characteristics than commercial aircraft. Military aircraft and engines also tend to be older and less efficient than commercial aircraft and produce more emissions. Engines are optimized for fuel consumption and power rates at a particular cruising altitude. At take-off, the engines are usually very inefficient and produce more emissions than when at the optimal cruising altitude. Older military aircraft like the B-52 and C-130 can leave a black smoke exhaust even at cruising altitude, while aircraft like the KC-135R with new engines produce an invisible exhaust plume. Typical pictures of aircraft exhaust emission are shown below.



Space launch vehicles and missiles produce a different type of exhaust than aircraft. The propulsion system on military rockets and missiles is usually made of solid rocket fuel. Missiles and rockets produce smoke plumes as a result of the solid fuel burning. The hot gases escaping from the motor can also create contrails, but the smoke and contrail combine to form a single exhaust plume. For more information on Air Force propulsion and fuels programs, see the Air Force Research Laboratory Propulsion Directorate at http://www.pr.afrl.af.mil/.



Chaff and Flares

Chaff and flares are defensive counter measures used on aircraft to confuse radar and heat seeking missiles. Chaff is used as a decoy for radar seeking missiles and is made of glass silicate fibers with an aluminum coating. The fibers are approximately 60% glass fiber and 40% aluminum by weight. The typical Air Force RR-188 chaff bundle contains about 150 g of chaff or about 5 million fibers. The fibers are 25 microns in diameter and typically 1 to 2 cm in length. In 1997, the Air Force used about 1.8 million bundles worldwide.

The amount of chaff released worldwide by all of the services is approximately 500 tons per year. Chaff falls to the earth at a settling velocity of approximately 30 cm per second. Atmospheric residence times range from 10 minutes for the majority of chaff released at 100 m to approximately 10 hours for chaff released at 10,000 feet. Chaff fibers experience little breakup before reaching the ground.

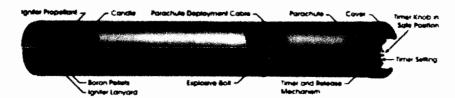
After the chaff is ejected from the aircraft and into the aircraft slipstream, the chaff packages burst open and the fibers scatter to form a radar-reflective cloud called a chaff corridor. Each chaff package is designed to simulate an aircraft. Several aircraft can create a chaff curtain, consisting of thousands of false targets, which confuse the radar guidance package on a missile so they are unable to locate the real targets within the chaff cloud.

Virtually all chaff fibers are 10-100 times larger than PM10 and PM2.5, the air particulates of concern for public health. The primary fiber size is usually too large to be inhaled by livestock, but if they are inhaled they do not penetrate far into the respiratory system and can be easily cleared out. The possible nutritional effects due to chaff ingestion and the risk is minimal to nil for both humans and livestock, considering the chemical composition of chaff (essentially identical to soil) and low chaff loading on the environment. Chaff decomposing in water has no adverse impacts on water chemistry or aquatic life.

Flares are of two types: decoy flares that protect aircraft from infrared missiles, and ground illumination flares. Decoy flares are typically made of magnesium that burns white-hot and are designed to defeat a missile's infrared (IR) tracking capability. The intense heat of the

pyrotechnic candle consumes the flare housing. Common aerial flares are: ALA-17/B, M-206, MJU-2, MJU-7 A/B, MJU-10/B, MJU-23/B, and RR-119.

Ground illumination flares, are designed to descend by parachute and provide up to 30 minutes of illumination of ground targets or activities. Typical flares are the LUU-1, LLU-5, and LLU-2B. A typical LLU-2B sectional is shown below.



The ground illumination flare enhances a pilot's ability to see targets while using Night Vision Goggles (NVGs). Flares burn at uneven rates and fluctuate in brightness and are not used as frequently as in the past as the intense light interferes with the newer NVGs more sensitive sensors.

The composition and materials of flares used by the military are similar to standard flares used for aerial, highway and marine purposes. (Skyline). While unburned decoy flares falling from high altitude could be dangerous, flares are designed to burn up during the descent (even the aluminum casing is burned).

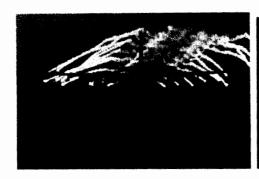
Chaff and flares are deployed on most Air Force aircraft from a common MJU-11 Chaff/Flare magazine that is integrated with the warning receiver (a device that alerts the aircraft a missile has locked onto the aircraft). The magazine has a capacity of 30 RR-188 or 30 M-206 flares.

A very thorough independent description of military systems, equipment, and capabilities is published by the American Federation of Scientists.

Typical chaff and flare deployments and patterns are shown in the following pictures.









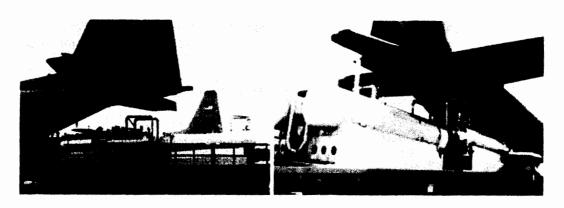


Aerial Spraying

There are some specific uses of commercial, private, and military aviation where chemicals are introduced in the atmosphere. The most common association of aerial chemical release is spraying for insects, either as crop dusting or mosquito prevention measures. These activities are typically performed at low altitude levels and produce a mist spray that drops to the earth's surface.



The only unit in the Air Force capable of aerial spray operations to control disease-carrying pests and insects is the AFRC's 910th Airlift Wing, Youngstown-Warren Air Reserve Station, Ohio (http://www.afrc.af.mil/units/910aw/default.htm). The aerial spray mission uses four specially configured C-130 Hercules shown below. Aerial spraying enables large parcels of land or water to be treated safely, quickly, accurately, and cheaply. This is the only fixed wing aerial-spray capability in the Department of Defense.



The mission started back in World War II, when legions of American GIs fell victim to malaria and dengue fever, diseases spread by mosquitoes. The mission was taken over from the active force in 1973. Although most of the unit's missions are initiated by the Department of Defense, its services are also requested by local, state and other federal agencies and coordinated the Center for Disease Control. The most common missions flown are for mosquito, sand flea and weed control. Several states have also requested support to combat grasshoppers and locusts. Aerial spray missions have been flown in Puerto Rico, Panama, Guam and the Azores.

The chemical compounds used for mosquito control are EPA controlled and the Air Force uses two primary brands; Dibrom and Anvil 10+10. Dibrom is manufactured by AMVAC Chemical Corporation and is classified as a Naled compound. Naled is an organophosphate insecticide that has been in use since 1959. It is used primarily for controlling adult mosquitoes but is also used on food and food crops, greenhouses and pet flea collars. Naled is applied using Ultra-Low Volume sprayers which dispense very fine aerosol droplets which kills the adult mosquito on contact. Naled is applies at a maximum aerial spray rate of 0.8 ounces of active ingredient per acre. Anvil 10+10 is manufactured by Clarke Mosquito Control Products, Inc and is a Sumithren, also known as a Synergized Synthetic Pyrethoid. Anvil 10+10 is applied using Ultra-Low Volume sprayers at a maximum aerial spray rate of 0.62 ounces of active ingredient per acre.

The chemical compounds used for herbicide weed control are EPA controlled and the Air Force uses Dupont Krovar I DF and Dow Agro Sciences Tordon K. Krovar I DF comes in granular form, is mixed with water and applied as an aerosol to control annual weeds at a rate of 4-6 pounds mixed with 40-100 gallons of water per acre. Tordon K is used as a herbicide to control broadleaf weeds, woody plants, and vines on non-crop areas such as forest planting sites, industrial manufacturing sites, rights-of-way such as electrical power lines, communications lines, pipelines, roadsides, railroads, and wildlife openings. Tordon K is applied at a maximum of 2 quarts per acre.

The 910th Airlift Wing has formed an Oil Dispersant Working Group, and is working with industry and government agencies to test aerial spray methods of controlling major offshore oil spills in coastal waters of the United States. The unit has six Modular Aerial Spray Systems (MASS) and four aircraft modified to accept the MAAS. Each MASS has a 2,000 gallon capacity and flow rate are set at 232 gallons per minute. The aircraft flies at 200 Knots Ground Speed at about 100 feet which covers a swath width of 100 feet for an average application rate of flow rate of 5 gallons per acre (variable 3-15 gallons per acre). Total spray-on time for 2,000 gallons lasts about 8 minutes and 30 seconds.

Photographs which show military aircraft with sprays coming from unusual locations on the aircraft are usually re-touched photos (a process that is easy to create using common computer programs).

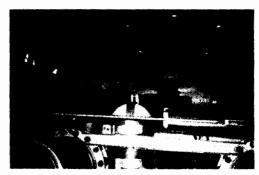


Cloud Seeding and Fire Suppression

For a number of years commercial companies have been involved in cloud seeding and fire suppression measures. Cloud seeding requires the release of chemicals in the atmosphere in an effort to have water crystals

attach themselves and become heavy enough to produce rain. The Air Force does not have a cloud seeding capability.

Fire suppression involves dumping chemicals onto a fire using cargo-type aircraft or helicopters. The 731st Airlift Squadron assigned to the 302nd Airlift Wing, Peterson Air Force Base, CO., is trained in the use of modular airborne fire fighting systems that help firefighting efforts of the U.S. Forest Service by dropping retardant chemicals directly onto fires. The unit's C-130s are loaded with a system designed to airdrop fire-retardant chemicals used in fighting forest fires and fertilizing the forest to generate quick



regrowth. The 302nd AW has conducted firefighting response in Colorado, California, Oregon and Idaho.



U.S. forest fires generally occur in desolate, almost inaccessible geographical areas. The U.S. Forest Service turned to air power to help its ground fire fighting units quickly contain and suppress these fires. Over the years, the forest service has developed a highly effective air-attack organization and air tanker fleet to deal with the forest fire emergency.

In 1970, however, numerous catastrophic forest fires erupted in southern California, severely overloading the

air tanker fleet's ability to cope with them all. This led to several U.S. Congressmen requesting the U.S. Air Force help the forest service by making military aircraft available as a back-up measure. This in turn led to the development of the Modular Airborne Fire Fighting System (MAFFS). The system is designed to quickly adapt military C-130 aircraft from a military role to a fire-suppression role.

Since 1974, the U.S. Air Force Reserve and Air National Guard units strategically located near high-incident forest fire areas have been equipped with these MAFFS units, and have sent selected aircrews to the aircrew training school for instruction in forest service air operations and procedures.

The MAFFS System is a modular, reusable airborne system for deploying water and fire retardant chemicals from aircraft in flight. It

consists of seven airbome modules and one ground air compressor module. The system can be loaded on a C-130 aircraft in two hours, and filled with retardant and compressed air in 15 to 20 minutes. The system is self-contained and requires no aircraft modifications. Each system weighs 10,500 pounds empty, and has a capacity of 2,700 gallons.

The entire load of retardant is discharged over a fire in 6 to 8 seconds.

Other AFRC aircraft shuttle Forest Service personnel and equipment to fire areas when the emergency requires a swift deployment to the fire line. This increased mobility allows more efficient use of Forest Service resources.

In-flight Emergency Fuel Release

Another common, but infrequent, procedure is the release, or venting, of fuel as a safety measure. If an in-flight emergency (IFE) is declared, a pilot will want to land the aircraft with as light a load as possible to prevent the possibility of damaging the aircraft and/or causing a fuel leak on landing. In order to lighten the fuel load a pilot can continue to fly until the fuel is burned or vent the fuel into the atmosphere. Fuel that is released, or vented, typically atomizes into a fine spray as it is released and typically evaporates before it reaches the ground. JP-8 jet fuel released at low altitudes appears as a fine mist and may not volatilize before reaching the ground surface. The release of fuel does not produce a contrail and appears more like a smoke pattern that dissipates quickly.

The "Chemtrail" Hoax

A hoax that has been around since 1996 accuses the Air Force of being involved in spraying the US population with mysterious substances and show various Air Force aircraft "releasing sprays" or generating unusual contrail patterns. Several authors cite an Air University research paper titled "Weather as a Force Multiplier: Owning the Weather in 2025" (http://www.au.af.mil/au/database/research/ay1996/acsc/96-025ag.htm) that suggests the Air Force is conducting weather modification experiments. The purpose of that paper was part of a thesis to outline a strategy for the use of a future weather modification system to achieve military objectives and it does not reflect current military policy, practice, or capability.

The Air Force's policy is to observe and forecast the weather. The Air Force is focused on observing and forecasting the weather so the information can be used to support military operations. The Air Force is not conducting any weather modification experiments or programs and has no plans to do so in the future.

The "Chemtrail" hoax has been investigated and refuted by many established and accredited universities, scientific organizations, and major media publications.

Claims and Facts

Claim: Long-lasting contrails are something new and they have abnormal characteristics.

Fact: Contrails can remain visible for very long periods of time with the lifetime a function of the temperature, humidity, winds, and aircraft exhaust characteristics. Contrails can form many shapes as they are dispersed by horizontal and vertical wind shear. Sunlight refracted or reflected from contrails can produce vibrant and eye-catching colors and patterns. Observation and scientific analysis of contrails and their duration date back to at least 1953.

Claim: Grid patterns of contrails in the sky are evidence of a systematic spraying operation.

Fact: The National Airspace System of the United States is orientated in an east-west and north-south grid with aircraft flying at designated 2000 foot increments of elevation. Contrails formed by aircraft may appear to form a grid as the winds disperse the contrails. More contrails are seen in recent years due to the growth in the civil aviation market. The FAA is responsible for the NAS and Air Force aircraft operate under the same rules and procedures as civilian aircraft when using the NAS.

Claim: There are reported outbreaks of illness after the appearance of "Chemtrails"

Fact: There is no such thing as a "Chemtrail". Contrails are safe and are a natural phenomenon. They pose no health hazard of any kind. If there are massive outbreaks of illnesses, your local health department should be able to tell you if it is an abnormal event. Local health departments generally network together when they start seeing problems. If there is a problem, the CDC will get involved.

Claim: Samples taken have shown the presence of the "DOD patented" bacteria pseudomonas fluorescens.

Fact: The bacteria claimed to be DOD developed and patented is actually a common, naturally occurring bacteria. The U.S. Patent Office (www.uspto.gov) lists 181 patents involving pseudomonas fluorescens, none of which are held by DOD.

Links to Related Sites

- FAA Office of Aviation Research http://research.faa.gov/aar/
- FAA Office of Environment and Energy http://aee.hq.faa.gov/
- DOT Bureau of Transportation Statistics http://www.bts.gov/
- Center For Disease Control and Prevention http://www.cdc.gov/
- EPA Office of Pesticide Programs http://www.epa.gov/pesticides
- International Civil Aviation Organization http://www.icao.int/
- Air Transport Association http://www.air-transport.org/
- Aerospace Industries Association http://www.aia-aerospace.org/
- Federation of American Scientists http://www.fas.org/index.html
- General Electric Aircraft Engines http://www.geae.net/
- Pratt and Whitney Aircraft Engines http://www.pratt-whitney.com/engines/
- Rolls-Royce Aircraft Engines http://194.128.225.11/defence/milp001.htm

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Appleman, H., 1953. The formation of exhaust condensation trails by jet aircraft. Bulletin of the American Meteorological Society 34: 14-20. Brewer, A.W., 1946. Condensation trails. Weather 1: 34-40.

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Pike, John, Aircraft Weapon Loads, Federation of American Scientists, 2000.

Aircraft and Contrails. EPA publication number EPA430-F-00-005. 6 pp EPA, 2000. (www.epa.gov/otaq/aviation.htm)

Layman's Library

Contrails - Contrails, or condensation trails, are "streaks of condensed water vapor created in the air by an airplane or rocket at high altitudes." (Webster's Dictionary). Contrails are the result of normal emissions of water vapor from jet engines. At high altitudes, water vapor condenses and turns into a visible cloud. Contrails form when hot humid air from jet engines mixes with the surrounding air in the atmosphere which is drier and colder. The mixing is a result of turbulence generated by the jet engine exhaust. The water vapor in the jet exhaust then condenses and forms a cloud. The rate at which contrails dissipate is entirely dependent upon weather conditions and altitude. If the atmosphere is near saturation, the contrail may exist for some time. Conversely, if the atmosphere is dry, the contrail will dissipate quickly.

Contrail Grid Patterns - Numerous contrails are usually over "air routes", or highways in the sky. Aircraft fly in all different directions at any time, and numerous contrails may seem to "crisscross". Although contrails may appear to cross, the trails can actually be from planes separated by significant altitude and time.

Chaff - Chaff are small bundles of aluminum coated fibers that create a large radar reflection. A radar seeking missile is unable to distinguish an aircraft from the chaff and loses the lock on the aircraft.

Chemtrails - Chemtrails is a term coined to suggest contrails are formed by something other than a natural process of engine exhaust hitting the cold air in the atmosphere.

Ethylene dibromide - Ethylene dibromide, or EDB, is a pesticide that was used commercially before being banned by the Environmental Protection Agency in 1983. During WW II, EDB was used as an additive in aviation gasoline to help stop lead in the aviation gasoline from plating out on valves. Jet fuels, including JP-8 have never contained EDB. Soil samples showing the presence of EDB are most likely residuals from previous use as a pesticide. Webster's dictionary definition of EDB: ": a colorless toxic liquid compound C2H4Br2 that is used chiefly as a fuel additive in leaded gasolines, that has been found to be strongly carcinogenic in laboratory

animals, and that was used formerly in the U.S. as an agricultural pesticide -- abbreviation EDB."

JP-8 Jet Fuel - JP-8 jet fuel consists of kerosene, a petroleum distillate fraction purchased to specification. The specification requires that the fuel producer meet a range of chemical and physical properties to ensure proper aircraft operation. Fuel additives are allowed, but are highly controlled. Additives include antioxidants, metal deactivators, corrosion inhibitors, fuel system icing inhibitor, and a static dissipater additive.

Rocket Exhaust - The exhaust plume generated by solid or liquid fueled rockets. Solid rocket motors are usually made of ammonium perchlorate and typically create light colored exhaust emissions. The exhaust is mainly carbon dioxide and water, but may also have high levels of hydrochloric acid formed, but which disperses rapidly. Liquid fuel rockets are generally kerosene and Liquid Oxygen (LOX) and produce an exhaust, which is darker and similar to aircraft exhaust. The exhaust is primarily carbon dioxide and water, but may contain nitrous oxides, sulfides, and soot particles.

Stratospheric Ozone - The ozone formed in the upper atmosphere through the interaction of the sun's energy and oxygen and which provides the natural shielding effect for the earth from UV rays. This ozone layer is susceptible to destruction by chlorinated compounds and is generally associated with the ozone hole over the Antarctic. Ozone in the lower atmosphere and ground level is generally a by-product of motor vehicle fuel combustion that forms NOx as a precursor which then forms ozone. This ozone is often seen as smog in most major cities.

Vapor Trails - The trail formed behind an aircraft as result of air flowing over a surface which creates a cavity in the air, similar to a boat propeller in water.



INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE





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